Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 | Confirmation No.: 5172

Filed: November 24, 2003 | Art Unit: 1796

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent | Examiner: Necholus Ogden, Jr.

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This Appeal Brief is submitted in triplicate to support the Notice of Appeal filed in this application on December 8, 2008. This Appeal Brief is accompanied by the fee for filing an Appeal Brief under 37 C.F.R. §1.17(b). Accordingly, this Appeal Brief is timely filed and no further fees are believed due.

Any additional required fee may be charged, or any overpayment credited, to Deposit Account No. 13-2855.

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II. REAL PARTY IN INTEREST

The real party in interest in this appeal is The Dial Corporation (Dial), Scottsdale, Arizona, the assignee of the entire right, title, and interest to the above-identified patent application. The assignment was recorded in the United States Patent and Trademark Office ("USPTO") at Reel 15159, Frame 0142 on April 1, 2004, which constitutes the entire chain of title from the inventors to Dial.

III. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellants, appellants' legal representative, or the assignee which will directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

IV. STATUS OF CLAIMS

A. HISTORY

This application was originally field with claims 1-24. Claims 25 and 26 were added to the application during prosecution.

B. CURRENT STATUS OF CLAIMS

Claims cancelled: 1, 4, 7, 8, and 10.

Claims withdrawn from consideration but not cancelled: None.

Claims pending: 2, 3, 5, 6, 9, and 11-26.

Claims allowed: None.

Claims rejected: 2, 3, 5, 6, 9, and 11-26.

C. CLAIMS ON APPEAL

The claims on appeal are claims 2, 3, 5, 6, 9, and 11-26.

V. STATUS OF AMENDMENTS

Appellants filed a Response to Office Action and a Request for Continued Examination on July 25, 2008. The response and claim amendments therein were entered. Accordingly, appellants understand that the current form of the claims are represented by the Response to Office Action of July 25, 2008, as reproduced in the Claims Appendix below.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

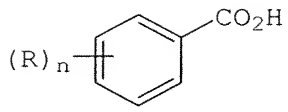
The present invention is directed to a method of reducing a bacteria and/or a virus population on a surface by contacting the surface with an antimicrobial composition. After 30 seconds of contact with the composition, the surface demonstrates a log reduction of at least 3 against *S. aureus* and/or *E. coli*. The method also demonstrates antiviral activity. The surface can be animate or inanimate.

Important features of the claimed composition are: (a) an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition, (b) the composition contains 0% to 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant, *and* (c) the composition contains a hydric solvent comprising dipropylene glycol. The claimed compositions demonstrate unexpected antibacterial and antiviral results for a composition lacking a second antimicrobial agent and a surfactant. In particular, the examples in the specification show an unexpectedly high antimicrobial efficacy when *both* an aromatic carboxylic as the sole antimicrobial agent *and* a claimed hydric solvent are present (see Examples 1, 3, 4, 7, and 9). Comparative Examples 2 and 8 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy. The examples also show that a minimum amount of hydric solvent is required in the composition to obtain a log 3 reduction in bacterial populations, as recited. Specification, page 25, lines 6-11.

The above features of the present invention are clearly set forth in independent claims 17 and 22, wherein a surface is contacted with an antimicrobial solution for 30 seconds to reduce bacteria population (claim 17) or a viral population (claim 22).

More particularly, claim 17 recites a method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 6, line 29 through page 7, line 12; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 2, 3, 5, 6, 9, 11-16, 18-21, 25, and 26 depend from claim 17.

Claim 2 recites that the antimicrobial composition comprises about 0.1% to about 5%, by weight, of the aromatic carboxylic acid. Specification, page 10, lines 9-12.

Claim 3 recites that the aromatic carboxylic acid of the antimicrobial composition has a pKa of about 2.5 to about 7. Specification, page 11, line 1 through page 12, line 8.

Claim 5 recites that the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof. Specification, page 11, line

15 through 12, line 8. Claim 6 recites that antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof. Specification, page 11, line 15 through page 12, line 8.

Claim 9 recites that the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol. Specification, page 24, lines 13-20 and page 25, Table of Example 4.

Claim 11 recites that the antimicrobial composition comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof. Specification, page 13, lines 15-22.

Claim 12 recites that the antimicrobial composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof. Specification, page 13, lines 15-22.

Claim 13 recites that the pH-adjusting compound is present in the antimicrobial composition in an amount of about 1% to about 5%, by weight, of the composition. Specification, page 13, line 29 through page 14, line 2.

Claim 14 recites that the antimicrobial composition has a pH of about 2 to about 5. Specification, page 13, lines 24-29.

Claim 15 recites that the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof. Specification, page 14, lines 14-21.

Claim 16 recites that the antimicrobial composition comprises

(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5. Specification, page 10, lines 12-15; page 12, lines 18-21; and page 13, lines 24-29.

Claim 18 recites that the antimicrobial composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*. Specification, page 6, line 29 through page 7, line 12.

Claim 19 recites that the antimicrobial composition achieves a log reduction of at least 3 in a viral population. Specification, page 7, lines 13-17.

Claim 20 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 21 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 16-19; and page 28, lines 19-28.

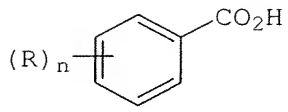
Claim 25, which depends from claim 16, recites that the antimicrobial carboxylic acid comprises salicylic acid. Specification, page 12, lines 4-8 and page 22, Example 1, lines 5-23.

Claim 26, which also depends from claim 16, recites that the antimicrobial composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof. Specification, page 13, lines 13-22.

Independent claim 22 recites a method of reducing a viral population on a surface comprising contacting the surface with a composition for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 7, lines 13-17; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 23 and 24 depend from claim 22.

Claim 23 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 24 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 10-19; and page 28, lines 19-28.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 2, 3, 5, 6, 9, and 11-26 would have been obvious under 35 U.S.C. §103 over Beerse et al. U.S. Patent No. 6,294,186 ('186).

For purposes of the issues on appeal, claims 2, 3, 5, 6, 9, and 11-26 are grouped and argued together.

VIII. ARGUMENT

A. INTRODUCTION

Appellants submit that the rejection issued in the final Office Action is in error, and that the present application is in condition for allowance. Appellants respectfully request the Board to review and reverse the rejection issued in the final Office Action.

B. PROPER BASIS FOR A §103(a) OBVIOUSNESS REJECTION

A determination that a claimed invention would have been obvious under §103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness include factors such as commercial success, long-felt but unresolved needs, the failure of others, and/or unexpected results achieved by the claimed invention. *Id.* Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the claimed subject matter pertains, who is presumed to have all prior art references in the field of the invention available to him/her. In *re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Furthermore, obviousness must be determined as of the time the invention was made and in view of the state of the art that existed at that time. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

The Patent Office must clearly articulate facts and reasons why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention's effective filing date. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (citing with approval In *re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")); see also MPEP §2143 ("The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of reason(s) why the claimed invention would have been obvious.").

To reach a proper determination under 35 U.S.C. §103(a), the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of appellants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search, and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon appellants' disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the *facts* gleaned from the prior art. MPEP §2142.

Furthermore, to establish a *prima facie* case of obviousness, the examiner must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to *identify* a *reason that would have prompted a person of ordinary skill in the relevant field to combine the elements* in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (emphasis added, *KSR*, *supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In *re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

As recently articulated by the Court of Appeals for the Federal Circuit in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 86 USPQ 2d, 1196, 1201-2 (Fed. Cir. 2008):

> "As this court has explained, however, a flexible TSM test remains the primary guarantee against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 [84 USPQ 2d 1929] (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.)."

Once the Patent Office properly sets forth a prima facie case of obviousness, the burden shifts to the appellants to come forward with evidence and/or arguments supporting patentability. *See In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is merely a showing of facts supporting the opposite conclusion. *In re Piasecki*, 745 F.2d 1468,1472 (Fed. Cir. 1984). Evidence rebutting a prima facie case of obviousness can include: (a) "evidence of unexpected results," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 1369 (Fed. Cir. 2007); (b) "evidence that the prior art teaches away from the claimed invention in any material respect," *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); and, (c) evidence of secondary considerations, such as commercial success or long-felt yet unmet needs, *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). The Patent Office must always consider such evidence supporting patentability. *See, e.g., In re Sullivan*, 498 F.3d 1345, 1352-53 (Fed. Cir. 2007) (reversing a Patent Office decision of obviousness because the Patent Office failed to consider the applicants' evidence rebutting a prima facie case of obviousness). If the Patent Office determines that such evidence is not compelling or is insufficient, then the Patent Office should specifically set forth the facts and reasoning supporting that determination. MPEP §2145 (8th Ed., Rev. 6, Sept. 2007).

C. REJECTION OF CLAIMS 2, 3, 5, 6, 9, AND 11-26 UNDER 35 U.S.C. §103 AS BEING OBVIOUS OVER THE '186 PATENT

Claims 2, 3, 5, 6, 9, and 11-26 stand rejected under 35 U.S.C. §103 as being obvious over the '186 patent. The examiner contends that the '186 patent renders the claimed methods obvious because the cited reference teaches compositions containing the same ingredients as the claimed compositions, and therefore are expected to provide similar characteristics. It is submitted that this rejection is in error and should be reversed.

As stated by the examiner in the Office Action of August 7, 2008 at pages 2 and 3:

> "It would have been obvious to one of ordinary skill in the art to expect the compositions of Beerse et al to exhibit efficacy against bacteria with a log 3 reduction for 30 seconds because Beerse et al teach compositions that maintain a log 2 reduction against viruses for 30 minutes to an hour and the artisan of ordinary skill would expect the compositions of Beerse et al to exhibit a greater reduction in a shorter interval of time, in the absence of a showing to contrary. Moreover, the compositions of Beerse et al teach the same ingredients as claimed for the purpose of making an antimicrobial composition, wherein the artisan of ordinary skill would reasonably expect similar characteristics."

Appellants traverse this rejection because the compositions of the '186 patent are not equivalent to the compositions recited in the present claims.

1. Disclosure of the '186 Patent

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog *and* a metal salt ('186 patent abstract). In particular, the '186 patent, at column 3, lines 32-48 states:

> "The present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a benzoic acid analog;
> b) a safe and effective amount of a metal salt; and
> c) a dermatologically acceptable carrier for the acid and salt wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid.
>
> In another embodiment, the present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a metal-benzoic acid analog complex; and
> b) a dermatologically acceptable carrier for said complex wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid."

The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

> "Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent *in addition to* the aromatic carboxylic acid.

The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. The '186 patent, at column 47, lines 18-54 states, in part:

> "Furthermore, Applicants have found that compositions which contain a benzoic acid analog and a dermatologically acceptable carrier and which are essentially free of metal salts are also effective in providing residual anti-viral efficacy. Accordingly, Applicants have also found that such compositions are also effective in providing residual anti-viral efficacy. Applicants have also found that such compositions are useful for providing residual antibacterial efficacy... These methods of the present invention each comprise the step of topically applying a composition comprising a safe and effective amount of benzoic acid analog and a dermatologically acceptable carrier wherein said composition is essentially free of metal salts. As used herein, "essentially free" means that any metal salts are present in levels which are not detectable by means typically used in the arts to detect such compounds. Preferably, such compositions are free of metal salts and the benzoic acid analog is selected from the group consisting of benzoic acid, salicylic acid..."

The '186 patent contains one example (Example 21) that is free of a metal salt. However, the composition of this example also contains a total of 10 wt% of surfactants *and* 1.50% para-chloro-meta-xylenol (a second antimicrobial agent). See '186 patent, column 20, lines 34 through column 22, line 37, and particularly, column 21, lines 59 and 60. The

definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

The "dermatologically acceptable carrier" can comprise an alcohol solution (column 9, lines 32-43). The alcohol can be a monohydric alcohol, dihydric alcohol, and combinations thereof, with C_2-C_{18} monohydric alcohols being preferred alcohols (column 9, lines 44-54). The sole specific disclosure of dihydric alcohols in the '186 patent is in Examples 16-18, wherein dipropylene glycol is present in an amount of 8%, by weight. Examples 16-18 of the '186 patent each incorporate a metal salt.

2. Rejection of Claims 2, 3, 5, 6, 9, and 11-26 under 35 U.S.C. §103 As Being Obvious Over the '186 Patent

The present claims recite methods of reducing bacteria and virus populations on a surface by contacting the surface with a composition containing an aromatic carboxylic acid as the *sole* antimicrobial agent in the composition. The composition also (a) has a pH of about 2 to about 5.5, (b) contains a hydric solvent comprising dipropylene glycol in a sufficient amount to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* of 30 seconds contact, and (c) 0% to 0.2%, by weight, of a surfactant (i.e., is essentially free of a surfactant). As demonstrated below, the compositions used in the claimed methods demonstrate unexpected results for a composition lacking a second antimicrobial agent and/or a surfactant. The '186 patent fails to teach or suggest a composition that demonstrates this combination of features.

Appellants particularly direct the Board's attention to the examples in the specification. Specifically, Examples 1-3 show that pH is important to achieve efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic acid alone, i.e., in the absence of a hydric solvent, is not efficacious (Ex. 3). By "not efficacious", it is meant that the claimed log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact is not achieved, for example, see specification, page 22, lines 17-19 and page 25, lines 4-11. See the Declaration of Earl P. Seitz (Seitz Declaration, paragraph 17) filed on July 25, 2008 and provided in the Evidence Appendix herein at pages A6- A10.

Example 4 of the specification illustrates that a minimum amount of hydric solvent is required to achieve the claimed log reduction of at least 3. As stated in the specification at page 25:

> "It is envisioned that a minimum amount of hydric solvent is needed in a composition to provide an AEI of at least 3, and this minimum amount is related to the identity of the hydric solvent, solution pH, and aromatic carboxylic acid concentration. The minimum amount of hydric solvent can be readily determined for any composition by the test criteria described in this example."

The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims *exclude* the presence of a metal salt that is taught as essential in the '186 patent. In particular, the claims clearly recite that the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. However, the sole example of this embodiment, i.e., Example 21, differs in *three* substantial ways from the present composition. First, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50%, by weight, of the phenolic antimicrobial para-chloro-meta-xylenol (PCMX). See the '186 patent, column 20, line 34 through column 22, line 37, and especially column 21, lines 59-60. This *phenolic* antimicrobial agent is excluded from the present claims, i.e., it is *not* an aromatic carboxylic acid.

Second, a major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Third, Example 21 of the '186 patent also is free of a hydric solvent, which is a presently claimed ingredient in an amount of about 10% to about 40%, by weight, of the composition, and which is required to provide a composition capable of providing an at least log 3 reduction in *S. aureus* and/or *E. coli* after 30 seconds of contact. The sole example of

the '186 patent that is free of a metal salt therefore is completely different from a composition recited in the present claims.

The '186 patent also discloses that the carrier can be an alcohol solution, i.e., monohydric and/or dihydric alcohols. The preferred alcohols are monohydric C2-C18 alcohols, and the only specifically named alcohols are ethanol, isopropanol, n-propanol, butanol, and mixtures thereof. See '186 patent, column 9, lines 44-51. In contrast, the present claims recite at least 10% of a hydric solvent comprising dipropylene glycol as the hydric solvent. Claim 9 is limited to dipropylene glycol as the hydric solvent in an amount of at least 20%, by weight. Although the '186 patent discloses dipropylene glycol in Examples 16-18, these examples each include (a) a metal salt and (b) the dipropylene glycol is present in too low an amount (8%, by weight) to provide a claimed log reduction of at least 3, as claimed, in the absence of a metal salt. It also must be noted that Examples 16-18 of the '186 patent each include a metal salt, which is *excluded* from the present claims. The other '186 patent examples referred to and relied upon by the examiner, i.e., Examples 4, 12, 14, and 15 are free of a hydric solvent and contain a metal salt (which is excluded from the present claims).

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition *and* the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant *and* the composition contains an amount of hydric solvent sufficient to achieve a log reduction of at least 3 against *S. aureus* and *E. coli* after 30 seconds contact.

In the Office Action, the examiner provides responses to appellants' previous arguments, and many of the statements show a definite hindsight reconstruction of appellants' invention. In particular, the examiner has selected isolated teachings (i.e., ingredients or lack of ingredients) from different examples of the '186 patent to reconstruct appellants' claimed composition, while *neglecting* other features present in the *same* example relied upon by the examiner.

For example, the examiner states at page 3, paragraphs 3 and 4, of the Office Action:

> "3. Applicant argues that examples 16, 18, and 21 do not suggests [sic] the embodiments of Beerse et al that do not require metal acid complex and further some examples suggest antimicrobial agents.
>
> 4. The examiner contends that non-preferred embodiments are indicative of obviousness and that the teachings of Beerse et al suggest compositions that do not requires [sic] metal-salt complex and further include solvents as claimed in their requisite proportions."

Appellants are somewhat unsure of the meaning of paragraph 3, however, statements in paragraph 4 are incorrect. Examples 16 and 18 each contain cupric chloride as the metal salt and 8%, by weight, dipropylene glycol, which is *less than* the claimed minimum amount (i.e., 10%, by weight) of hydric solvent, i.e., do *not* "include solvents as claimed in their requisite proportions."

With respect to compositions that do not require a metal-salt complex, Example 21 is free of a metal-salt complex, but contains a high amount (1.5%, by weight) of PCMX to boost antimicrobial activity. Note that Examples 22-25 grouped with Example 21 *each* contain a metal salt, and each *omits* a second antimicrobial compound, because the metal salt provides the boost in antimicrobial activity. In addition, the '186 patent contains more than merely suggesting embodiments with a second antimicrobial agent. In fact, the '186 patent *specifically* teaches the presence of a second antimicrobial agent when a metal salt is omitted. The para-chloro-meta-xylenol of Example 21 of the '186 patent *is* an antimicrobial agent as specifically disclosed in the '186 patent at column 21, lines 59-60.

The examiner states at page 4, paragraphs 7 and 8, of the Office Action:

> "7. Applicant argues that Beerse et al teach that the addition of a metal-acid complex acts as an additional anti-microbial agent.
>
> 8. The examiner contends that applicant's claims are bound by the transitional phrase of "comprising [sic] which permits the inclusion of additional components not specified in the claim. Moreover, as stated by applicant", Beerse et al do not require metal-salts in all of the embodiments and specifically suggest that the embodiments free of metal salts are effective in provide [sic] residual anti-viral

> efficacy (col. 47, lines 18-55) Therefore, Beerse et al do not require a metal-salt component as suggested by applicant, and further applicant's claims permit the use of additional ingredients not specified."

The metal salt clearly acts as a second antimicrobial agent as set forth in the '186 patent at column 7, lines 60-65. With respect to the contention that the term "comprising" allows additional components to be included in the composition, it must be pointed out that the claims specifically are limited to the aromatic carboxylic acid being the *sole* antimicrobial agent. Additional antimicrobial agents are excluded, e.g.., the metal salts taught in the '186 patent as antimicrobial agents. See Evidence Appendix, Seitz Declaration, paragraphs 7, 12, and 15, and '186 patent, column 7, lines 60-65.

First, appellants did not state that the metal salt free embodiments of the '186 patent were efficacious. This is unknown to appellants. The sole embodiment is Example 21, which contains 10%, by weight, surfactant and 1.5%, by weight, of a second antimicrobial agent, i.e., PCMX. Furthermore, *no* efficacy data is provided in the '186 patent for Example 21. The '186 patent may contend that the second embodiment of the disclosure is efficacious in the absence of surfactant and/or second antimicrobial agent, but has neither demonstrated such efficacy nor exemplified any such efficacious composition.

With respect to the examiner's comment that the '186 patent does not require a metal salt component, the only example free of a metal salt has both (a) 1.5 wt % of a second phenolic antimicrobial agent and (b) 10 wt % of a surfactant. Although the '186 patent at column 47, lines 18-54 suggests use of a benzoic acid analog in the absence of a metal salt, the reference *explicitly* teaches that a second antimicrobial agent is present to add to the efficacy of the composition. Therefore, the phenolic antimicrobial agent present in Example 21 provides a boost in antimicrobial activity because the metal salt is absent. A presently claimed composition is *free* of both a second antimicrobial agent and a surfactant.

At pages 4 and 5 of the Office Action, paragraphs 9-11, the examiner further states:

> "9. Applicant argues that Beerse et al fail to suggest a surfactant having 0 to 0.2%; and 5 to 50% by weight of a hydric solvent.

> 10. The examiner respectfully disagrees and directs applicant's attention to column 27, lines 55-60, which teaches less than 10% by weight of surfactants are needed. With respect to the hydric solvent, Beerse et al. teach that said solvent is present in an amount from 0-95% (column 9, lines 44-55).
>
> 11. Applicant argues that example 21 does not comprise a metal-salt but also does suggest high levels of surfactants."

First, the '186 patent, at column 27, lines 56-59, actually states that *co-surfactants* are present at less than 10% by weight, i.e., "*Co-surfactants* consisting of *additional* anionic, nonionic, cationic, and amphoteric or zwitterionic surfactants can *also* be included, but typically comprise less than 10% by weight of the composition" (emphasis added). Prior to this limited disclosure, the '186 patent discloses innumerable surfactants at columns 22-27. The disclosure relating to co-surfactants relates to *additional* surfactants that *also* can be included with a surfactant. Accordingly, the examiner's reliance on column 27, lines 56-59 is misplaced. Moreover, the '186 patent fails to disclose a composition essentially (a) free of a surfactant, (b) free of a metal salt, *and* (c) free of a second antimicrobial agent. The examiner's reasoning is an example of hindsight reconstruction wherein an isolated statement is used to support a rejection without a consideration either of the claimed invention as a whole or the *complete* teachings of the reference.

In addition, Example 21 does not "suggest" high levels of surfactants. To be precise, Example 21 *explicitly teaches* 5.0% ammonium lauryl sulfate and 5.0% ammonium laureth-3 sulfate, or 10.0% total surfactant, by weight. This is *50* times the claimed maximum of surfactant.

At page 5 of the Office Action, paragraph 12, the examiner states:

> "The examiner contends that a reference does not need to teach each of the components in an example to be indicative of obviousness. The general teaching of Beerse et al states that metal –salt complex is not require [sic] to perform as suggested (col. 47, lines 18-55). Moreover, Beerse et al teach several embodiments that do not require surfactants (see examples 4, 12, 14-15, 16-18)."

The examiner appears to be saying that as long as individual ingredients of a composition can be found in a reference, then a claim can be found obvious. In looking at different embodiments of the '186 patent, the examiner is focusing on individual ingredients that may or may not be present, then adding the various ingredients together or deleting ingredients, to arrive at a conclusion of obviousness. The examiner has failed to clearly articulate *facts* as to the way the claimed invention "as a whole" would have been obvious to a person skilled in the art. In particular, the examiner has failed to consider the claimed invention as a whole, as opposed to its individual ingredients, and has failed to consider the unpredictability in the art, wherein changing the identity of an ingredient, or its actual or relative amount in a composition, can substantially influence antimicrobial efficacy. For example, see the examples in the present application. While the examiner appears to rationalize his conclusion of obviousness, the examiner does not articulate facts to support the asserted rationale. MPEP §2143.

The examiner is "cherry picking" individual ingredients from various portions and examples of the '186 patent without considering either the entire teaching of the embodiments in the '186 patent or the claimed invention as a whole. The sole explicit teaching of a composition that is free of a metal salt in the '186 patent (Example 21) contains 10 wt % of a surfactant and 1.5 wt. % of a second antimicrobial agent, *both* of which are excluded from the present claims. The examples relied upon by the examiner (i.e., 4, 12, and 14-18) *all* are free of a surfactant, but all *contain* a metal salt, which is excluded from the present claims.

In general, the examiner's reasoning also is inconsistent. To support exclusion of a metal salt, the examiner relies upon the limited general teachings of the '186 patent at column 47, lines 18-55, but neglects the specific teaching on Example 21. However, to support exclusion of a surfactant, the examiner neglects the extensive general teachings at *columns* 22-27 of the '186 patent to include a surfactant, but relies upon specific examples to exclude a surfactant. Overall, it is submitted that the '186 patent would *not* have *reasonably* suggested to a person skilled in the art to (a) exclude a second antimicrobial agent *and* (b) exclude surfactants *and* (c) exclude a metal salt *and* (d) include a sufficient amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact.

The examiner contends that testing against comparative examples is necessary to support patentability. At page 5 of the Office Action, paragraph 13, the examiner states:

> "13. The Declaration under 37 CFR 1.132 filed 7-25-2008 is insufficient to overcome the rejection of claims2-3 [sic], 5-6, 9, 11-26 based upon Beerse et al as set forth in the last Office action because: Declarant states an opinion of Beerse et al that is not supported by factual evidence which compares the closest prior art of record against the claimed invention."

However, appellants are not claiming an improvement over the '186 patent, but are claiming a method using an entirely different composition. The '186 patent contains no objective evidence of efficacy, but merely a definition of "residual antibacterial activity" at column 4, lines 22-39, and "Analytical Methods" at columns 44-46. However, even assuming *arguendo* that the '186 patent compositions are efficacious, comparing the present compositions to the '186 patent composition would serve little purpose. The compositions of the '186 patent arguably would be shown to be efficacious, and appellants already have shown that the claimed compositions are efficacious.

The present invention is a discovery that, contrary to the '186 patent, the claimed composition is efficacious in the *absence* of a metal salt, in the *absence* of a surfactant, and in the *absence* of any other second antimicrobial agent. The '186 patent fails to lead, or provide any apparent reason for, a person skilled in the art to make these multiple jumps in reasoning, and *then* include a sufficient amount of a claimed hydric solvent to provide the claimed log reduction of *S. aureus* and/or *E. coli* after 30 seconds contact.

More particularly, the present invention is demonstrated in the examples, wherein it is shown that an aromatic carboxylic acid or a hydric solvent *alone* does not provide a high antimicrobial efficacy, as claimed. Both the aromatic carboxylic acid and hydric solvent are needed to achieve a high antimicrobial efficacy, and a sufficient amount of the hydric solvent also is needed (see specification, Example 4).

In effect, appellants *have* provided comparative testing to the closest prior art. If one takes a composition from the '186 patent, and following the examiner's strained reasoning, then excludes the metal salt *and* a surfactant *and* any other second antimicrobial

agent, the resulting composition would be those tested in Examples 1, 3, and 4. These examples show that simply excluding one or more of these components does *not* provide a composition having the claimed efficacy. What is needed is a combination of aromatic carboxylic acid and a sufficient amount of hydric solvent, as claimed. It was appellants that made the inventive discovery of including a hydric solvent in the claimed amounts to provide a highly efficacious composition for use in the claimed method. This discovery is neither taught nor suggested in the '186 patent.

The presently claimed invention clearly exhibits unexpected results, even when the essential metal salt of the '186 patent is omitted. In particular, the present examples show an unexpectedly high antimicrobial efficacy when both an aromatic carboxylic *and* a claimed hydric solvent are present (see Examples 1, 4, 7, and 9). Comparative Examples 2 and 3 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy.

At page 6 of the Office Action, the "examiner contends that the general teaching of Beerse et al. states that the metal-salt complex is not require [sic] to perform as suggested". However, the only disclosure of the '186 patent supporting the statements at column 47, lines 18-54, is Example 21, wherein a *second* antimicrobial agent, i.e., PCMX, is utilized to enhance the antimicrobial activity of the benzoic acid analog. The substantial differences between Example 21 of the '186 patent and the present compositions are set forth above, and in the Seitz Declaration (Evidence Appendix, paragraphs 7-16), showing that the comparison between a composition of the '186 patent and a claimed composition would be meaningless.

The differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. In fact, the '186 patent fails to support a *prima facie* obviousness rejection over the present claims. Simply put, the '186 patent provides no apparent reason to modify the '186 patent as suggested by the examiner with any reasonable expectation of providing an efficacious antibacterial method. The '186 patent stresses the necessity of either including a metal salt or using another second antimicrobial agent in the composition in order to achieve an enhanced antimicrobial action. For example, the '186 patent includes 42 examples, of which 41 contain a metal salt as an

antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant *and* is lacking a hydric solvent *and* contains a second antimicrobial agent. The '186 patent fails to teach or suggest a composition that (a) omits a metal salt and other additional antimicrobial agents, *and* (b) is essentially free of a surfactant, *and* (c) includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not have had any apparent reason to omit a metal salt *and* omit a surfactant *and* include a claimed hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

To establish a *prima facie* case of obviousness, *all three* requirements recited in MPEP §2143 must be satisfied: (1) the prior art reference or combination of references must teach or suggest *all the limitations* of the claims to those of ordinary skill in the art. See *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."); (2) the prior art relied upon must contain some suggestion or incentive, coupled with knowledge generally available in the art at the time of the invention, that would have motivated those of ordinary skill in the art to modify a reference or combine the references. See, *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385, 58 USPQ2d 1286, 1293 (Fed. Cir. 2001) ("in holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in a way that would produce the claimed invention."); *and* (3) the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

In the present application, the '186 patent fails to teach or suggest all the limitations of the claims to those of ordinary skill in the art, i.e., an aromatic carboxylic acid as the sole antimicrobial agent, the claimed minimum amount of dipropylene glycol, and the claimed amount of surfactant.

The '186 patent also fails to provide an apparent reason to modify the teachings of the reference and arrive at the present invention. The '186 patent has a limited disclosure that a metal ion can be excluded from the composition, but the reference fails to

teach that an aromatic carboxylic acid can be used as the sole antimicrobial agent. The '186 patent explicitly teaches using a second antimicrobial agent when the metal ion is excluded. The '186 patent also teaches using a high amount of surfactant in the absence of a metal ion, and fails to teach dipropylene glycol in the absence of a metal ion. Also see Seitz Declaration, Evidence Appendix, paragraphs 8-18.

The proposed modifications of the '186 patent to arrive at the present invention also would not have a reasonable expectation of success, as seen through the eye of a person skilled in the art. See Seitz Declaration, Evidence Appendix, paragraph 18.

The '186 patent therefore fails to meet the criteria set forth as MPEP §2143, and accordingly, a *prima facie* case of obviousness has not been made and the rejection should be withdrawn.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be reversed.

IX. CONCLUSION

In view of the foregoing remarks, appellants respectfully request that the Board reverse the final rejection of claims 2, 3, 5, 6, 9, and 11-26, and that all pending claims should be allowed.

Dated: February 9, 2009

Respectfully submitted,

By _____

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CLAIMS APPENDIX

Claims on Appeal in Application Serial No. 10/720,862

1. (Cancelled)

2. (Previously presented) The method of claim 17 comprising about 0.1% to about 5%, by weight, of the aromatic carboxylic acid.

3. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid has a pKa of about 2.5 to about 7.

4. (Cancelled)

5. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof

6. (Previously presented) The method of claim 17 wherein the antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof.

7. (Cancelled)

8. (Cancelled)

9. (Previously presented) The method of claim 17 wherein the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol.

10. (Cancelled)

11. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof.

12. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof.

13. (Previously presented) The method of claim 17 wherein the pH-adjusting compound is present in an amount of about 1% to about 5%, by weight, of the composition.

14. (Previously presented) The method of claim 17 having a pH of about 2 to about 5.

15. (Previously presented) The method of claim 17 wherein the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof.

16. (Previously presented) The method of claim 17 comprising:

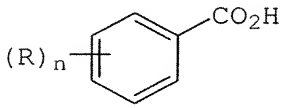
(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5.

17. (Previously presented) A method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

18. (Original) The method of claim 17 wherein the composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*.

19. (Original) The method of claim 17 wherein a log reduction of at least 3 is achieved in a viral population.

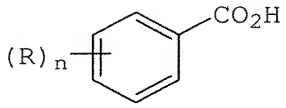
20. (Original) The method of claim 19 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

21. (Original) The method of claim 17 wherein the surface is a skin of a mammal.

22. (Previously presented) A method of reducing a viral population on a surface comprising contacting the surface with a composition of for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

23. (Original) The method of claim 22 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

24. (Original) The method of claim 22 wherein the surface is a skin of a mammal.

25. (Previously presented) The method of claim 16 wherein the antimicrobial carboxylic acid comprises salicyclic acid.

26. (Previously presented) The method of claim 16 wherein the composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof.

EVIDENCE APPENDIX

Declaration of Earl P. Seitz under 37 C.F.R. §1.132, filed July 25, 2008.

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 | Confirmation No.: 5172

Filed: November 24, 2003 | Art Unit: 1751

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent | Examiner: N. Ogden

DECLARATION OF EARL P. SEITZ UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

NOW COMES EARL P. SEITZ, Declarant herein, and states as follows:

1. I am a coinventor of the invention disclosed and claimed in the above-identified patent application.

2. I have been employed by The Dial Corporation (Dial), Scottsdale, Arizona, since 1978. I was a Research Manager of various technology and product development groups at Dial from 1980 to 1994. I am presently a Research Fellow at Dial, and have held this position since 1994. I am engaged in the research and development of personal care products, including compositions containing topically active components. In 2001, I was awarded Dial's R&D's highest technical award, the Robert E. Casely Award for Excellence in Innovation.

3. I received a Ph.D. in organic chemistry from Oregon State University, Corvallis, Oregon (1977), and a B.S. in chemistry from Texas Christian University, Fort Worth, Texas (1968). I also served in the U.S. Navy from 1969-1972, and held a post-doctoral position at The University of Wisconsin, Madison, WI in 1977 and 1978.

4. I have conducted research in the fields of skin cleansers and related surfactant-based compositions, including topically active and antibacterial compositions. I am a named inventor on seven U.S. patents involving technology disclosed in the above-identified patent application.

5. I have read and understand the Office Action dated March 28, 2008, which was issued in connection with U.S. Patent Application Serial No. 10/720,862. I also have read and understand the following patent cited by the examiner in U.S.S.N. 10/720,862: Beerse et al. U.S. Patent No. 6,294,186 ('186)).

6. Claims 2, 3, 5, 6, 9, and 11-26, all of the claims in the application, have been rejected as being obvious over the '186 patent. The basis of this rejection is that a skilled person would expect the claimed compositions to exhibit a similar antibacterial activity to compositions of the '186 patent because the '186 patent teaches the "same" ingredients. Contrary to the examiner's assertion, the compositions disclosed in the '186 patent are substantially different from the compositions recited in the presently-claimed methods.

7. The '186 patent describes and claims compositions comprising an antimicrobial agent. The title of the specification of the '186 patent is "Antimicrobial Compositions Comprising a Benzoic Acid Analogue and a Metal Salt". The '186 patent explicitly teaches that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states that "[W]ithout being limited by theory, it is believed that the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide the synergistic immediate and residual anti-viral and anti-bacterial efficacy to surfaces to which such compositions are applied" ('186 patent, column 7, lines 60-65).

8. The '186 patent contains 42 examples. Of these 42 examples, 41 contain a metal salt as an antimicrobial agent in addition to the aromatic carboxylic acid.

9. The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. This embodiment is identified by one sole example, namely

Example 21 in the '186 patent. However, the composition of this example also contains a total of 10 weight per cent of surfactants and 1.50% para-chloro-meta-xylenol, which is a second antimicrobial agent.

10. With regard to a hydric solvent, the '186 patent recites that a carrier for the disclosed composition can be an alcohol (see for example, column 9, lines 33-54 of the '186 patent). The sole disclosure in the '186 patent of dipropylene glycol, as claimed in the present invention, is in Examples 16 to 18. In these examples, the amount of dipropylene glycol is 8% by weight. Examples 16 to 18 of the '186 patent also include a metal salt, which is excluded from the present claims.

11. As stated above, the presently claimed composition includes aromatic carboxylic acid as the *sole* antimicrobial agent, an amount of hydric solvent, and 0% of 0.2% by weight of a surfactant. Having read the '186 patent, I can find no disclosure or suggestion that would lead a person skilled in the art to the presently claimed composition.

12. Moreover, the '186 patent *explicitly* teaches that the metal salt is an essential ingredient in the first embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims exclude the presence of a metal salt that is taught as essential in the '186 patent.

13. In the second embodiment of the '186 patent, a metal salt is absent. However, the sole example of this embodiment, i.e., Example 21, differs in three substantial ways from the presently claimed composition. Firstly, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50% by weight of the additional antimicrobial agent para-chloro-meta-xylenol (PCMX), i.e., a phenolic antimicrobial agent. This antimicrobial agent is excluded from the claims of the patent application in suit, i.e., it is not an aromatic carboxylic acid.

14. Secondly, Example 21 in the '186 patent contains a high amount of surfactant (10 weight per cent). In contrast, the present claims recite a composition having 0% to 0.2% by weight of a surfactant. Thirdly, Example 21 of the '186 patent is free of a hydric solvent, which is required in the claims of the application.

15. In summary, it is my opinion that the '186 patent teaches that a metal salt is essential to provide a synergistic effect, as a second microbial agent together with a first aromatic antimicrobial agent. As a skilled person, when reading this document I am told that the metal salt is essential for performing the invention of the '186 patent. In view of the teaching of the '186 patent that the metal salt provides a synergistic effect, it would be my belief on reading this document that omitting the metal salt would cause the invention of the '186 patent to fail, i.e., not provide sufficient antimicrobial action. Further, if a metal salt is excluded, the '186 patent then teaches me that a different second antimicrobial agent, e.g., PCMX, must be present to be efficacious, as in Example 21 of the '186 patent.

16. However, the disclosure of the '186 patent is inconsistent and has one example in which the metal salt is omitted, despite the fact that the document appears to be geared toward compositions containing a metal salt. However, this embodiment is substantially different from the composition of the present claims and it is meaningless to compare Example 21 with the compositions of the invention, given that the example is so different from the claimed invention. Moreover, Example 21 also contains a further antimicrobial agent to provide an enhanced antimicrobial effect in view of the absence of a metal salt.

17. The efficacy of the present invention is demonstrated by the examples in the specification. Examples 1-3 show that pH is important to enhance efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic alone, i.e., in the absence of a hydric solvent, is not efficacious.[1] Example 4 shows that a minimum amount of hydric solvent is required to achieve a log reduction of at least 3, as claimed. Example 9 shows that the method and composition are highly effective in reducing viral populations.

18. These efficacious results are achieved by using compositions free of a metal salt, essentially free of a surfactant, and containing an aromatic carboxylic acid as the sole antimicrobial agent in the composition. A person skilled in the art, after reading the '186 patent, would not have considered making any of these modifications, let alone all three, and still expect to provide a log reduction against *S. aureus* and/or *E. coli* of at least three.

[1] Efficacy is measured as a log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact.

19. The compositions claimed in the present application require a sole antimicrobial agent and is essentially free of an optional surfactant. The inventors of the present application have determined using their inventive skill that an antimicrobial composition can be effective using a sole antimicrobial agent without the mandatory metal salt of the '186 patent (to provide synergistic activity) or a second antimicrobial agent. Despite not having *either of* these ingredients, the claimed compositions are surprisingly effective.

20. The use of a single antimicrobial agent in the present application is an advantage, not least in terms of the resulting commercial product and ease of production of the product.

21. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Dated: 24 JULY, 2008

Earl P. Seitz

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 | Confirmation No.: 5172

Filed: November 24, 2003 | Art Unit: 1796

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent | Examiner: Necholus Ogden, Jr.

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This Appeal Brief is submitted in triplicate to support the Notice of Appeal filed in this application on December 8, 2008. This Appeal Brief is accompanied by the fee for filing an Appeal Brief under 37 C.F.R. §1.17(b). Accordingly, this Appeal Brief is timely filed and no further fees are believed due.

Any additional required fee may be charged, or any overpayment credited, to Deposit Account No. 13-2855.

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II. REAL PARTY IN INTEREST

The real party in interest in this appeal is The Dial Corporation (Dial), Scottsdale, Arizona, the assignee of the entire right, title, and interest to the above-identified patent application. The assignment was recorded in the United States Patent and Trademark Office ("USPTO") at Reel 15159, Frame 0142 on April 1, 2004, which constitutes the entire chain of title from the inventors to Dial.

III. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellants, appellants' legal representative, or the assignee which will directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

IV. STATUS OF CLAIMS

A. HISTORY

This application was originally field with claims 1-24. Claims 25 and 26 were added to the application during prosecution.

B. CURRENT STATUS OF CLAIMS

Claims cancelled: 1, 4, 7, 8, and 10.

Claims withdrawn from consideration but not cancelled: None.

Claims pending: 2, 3, 5, 6, 9, and 11-26.

Claims allowed: None.

Claims rejected: 2, 3, 5, 6, 9, and 11-26.

C. CLAIMS ON APPEAL

The claims on appeal are claims 2, 3, 5, 6, 9, and 11-26.

V. STATUS OF AMENDMENTS

Appellants filed a Response to Office Action and a Request for Continued Examination on July 25, 2008. The response and claim amendments therein were entered. Accordingly, appellants understand that the current form of the claims are represented by the Response to Office Action of July 25, 2008, as reproduced in the Claims Appendix below.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

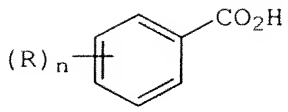
The present invention is directed to a method of reducing a bacteria and/or a virus population on a surface by contacting the surface with an antimicrobial composition. After 30 seconds of contact with the composition, the surface demonstrates a log reduction of at least 3 against *S. aureus* and/or *E. coli*. The method also demonstrates antiviral activity. The surface can be animate or inanimate.

Important features of the claimed composition are: (a) an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition, (b) the composition contains 0% to 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant, *and* (c) the composition contains a hydric solvent comprising dipropylene glycol. The claimed compositions demonstrate unexpected antibacterial and antiviral results for a composition lacking a second antimicrobial agent and a surfactant. In particular, the examples in the specification show an unexpectedly high antimicrobial efficacy when *both* an aromatic carboxylic as the sole antimicrobial agent *and* a claimed hydric solvent are present (see Examples 1, 3, 4, 7, and 9). Comparative Examples 2 and 8 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy. The examples also show that a minimum amount of hydric solvent is required in the composition to obtain a log 3 reduction in bacterial populations, as recited. Specification, page 25, lines 6-11.

The above features of the present invention are clearly set forth in independent claims 17 and 22, wherein a surface is contacted with an antimicrobial solution for 30 seconds to reduce bacteria population (claim 17) or a viral population (claim 22).

More particularly, claim 17 recites a method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 6, line 29 through page 7, line 12; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 2, 3, 5, 6, 9, 11-16, 18-21, 25, and 26 depend from claim 17.

Claim 2 recites that the antimicrobial composition comprises about 0.1% to about 5%, by weight, of the aromatic carboxylic acid. Specification, page 10, lines 9-12.

Claim 3 recites that the aromatic carboxylic acid of the antimicrobial composition has a pKa of about 2.5 to about 7. Specification, page 11, line 1 through page 12, line 8.

Claim 5 recites that the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof. Specification, page 11, line

15 through 12, line 8. Claim 6 recites that antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof. Specification, page 11, line 15 through page 12, line 8.

Claim 9 recites that the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol. Specification, page 24, lines 13-20 and page 25, Table of Example 4.

Claim 11 recites that the antimicrobial composition comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof. Specification, page 13, lines 15-22.

Claim 12 recites that the antimicrobial composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof. Specification, page 13, lines 15-22.

Claim 13 recites that the pH-adjusting compound is present in the antimicrobial composition in an amount of about 1% to about 5%, by weight, of the composition. Specification, page 13, line 29 through page 14, line 2.

Claim 14 recites that the antimicrobial composition has a pH of about 2 to about 5. Specification, page 13, lines 24-29.

Claim 15 recites that the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof. Specification, page 14, lines 14-21.

Claim 16 recites that the antimicrobial composition comprises

(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5. Specification, page 10, lines 12-15; page 12, lines 18-21; and page 13, lines 24-29.

Claim 18 recites that the antimicrobial composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*. Specification, page 6, line 29 through page 7, line 12.

Claim 19 recites that the antimicrobial composition achieves a log reduction of at least 3 in a viral population. Specification, page 7, lines 13-17.

Claim 20 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 21 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 16-19; and page 28, lines 19-28.

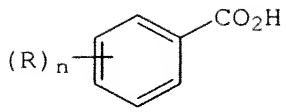
Claim 25, which depends from claim 16, recites that the antimicrobial carboxylic acid comprises salicylic acid. Specification, page 12, lines 4-8 and page 22, Example 1, lines 5-23.

Claim 26, which also depends from claim 16, recites that the antimicrobial composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof. Specification, page 13, lines 13-22.

Independent claim 22 recites a method of reducing a viral population on a surface comprising contacting the surface with a composition for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 7, lines 13-17; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 23 and 24 depend from claim 22.

Claim 23 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 24 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 10-19; and page 28, lines 19-28.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 2, 3, 5, 6, 9, and 11-26 would have been obvious under 35 U.S.C. §103 over Beerse et al. U.S. Patent No. 6,294,186 ('186).

For purposes of the issues on appeal, claims 2, 3, 5, 6, 9, and 11-26 are grouped and argued together.

VIII. ARGUMENT

A. INTRODUCTION

Appellants submit that the rejection issued in the final Office Action is in error, and that the present application is in condition for allowance. Appellants respectfully request the Board to review and reverse the rejection issued in the final Office Action.

B. PROPER BASIS FOR A §103(a) OBVIOUSNESS REJECTION

A determination that a claimed invention would have been obvious under §103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness include factors such as commercial success, long-felt but unresolved needs, the failure of others, and/or unexpected results achieved by the claimed invention. *Id.* Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the claimed subject matter pertains, who is presumed to have all prior art references in the field of the invention available to him/her. In *re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Furthermore, obviousness must be determined as of the time the invention was made and in view of the state of the art that existed at that time. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

The Patent Office must clearly articulate facts and reasons why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention's effective filing date. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (citing with approval In *re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")); see also MPEP §2143 ("The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of reason(s) why the claimed invention would have been obvious.").

To reach a proper determination under 35 U.S.C. §103(a), the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of appellants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search, and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon appellants' disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the *facts* gleaned from the prior art. MPEP §2142.

Furthermore, to establish a *prima facie* case of obviousness, the examiner must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to *identify* a *reason that would have prompted a person of ordinary skill in the relevant field to combine the elements* in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (emphasis added, *KSR*, *supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In *re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

As recently articulated by the Court of Appeals for the Federal Circuit in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 86 USPQ 2d, 1196, 1201-2 (Fed. Cir. 2008):

> "As this court has explained, however, a flexible TSM test remains the primary guarantee against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 [84 USPQ 2d 1929] (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.)."

Once the Patent Office properly sets forth a prima facie case of obviousness, the burden shifts to the appellants to come forward with evidence and/or arguments supporting patentability. *See In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is merely a showing of facts supporting the opposite conclusion. *In re Piasecki*, 745 F.2d 1468,1472 (Fed. Cir. 1984). Evidence rebutting a prima facie case of obviousness can include: (a) "evidence of unexpected results," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 1369 (Fed. Cir. 2007); (b) "evidence that the prior art teaches away from the claimed invention in any material respect," *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); and, (c) evidence of secondary considerations, such as commercial success or long-felt yet unmet needs, *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). The Patent Office must always consider such evidence supporting patentability. *See, e.g., In re Sullivan*, 498 F.3d 1345, 1352-53 (Fed. Cir. 2007) (reversing a Patent Office decision of obviousness because the Patent Office failed to consider the applicants' evidence rebutting a prima facie case of obviousness). If the Patent Office determines that such evidence is not compelling or is insufficient, then the Patent Office should specifically set forth the facts and reasoning supporting that determination. MPEP §2145 (8th Ed., Rev. 6, Sept. 2007).

C. REJECTION OF CLAIMS 2, 3, 5, 6, 9, AND 11-26 UNDER 35 U.S.C. §103 AS BEING OBVIOUS OVER THE '186 PATENT

Claims 2, 3, 5, 6, 9, and 11-26 stand rejected under 35 U.S.C. §103 as being obvious over the '186 patent. The examiner contends that the '186 patent renders the claimed methods obvious because the cited reference teaches compositions containing the same ingredients as the claimed compositions, and therefore are expected to provide similar characteristics. It is submitted that this rejection is in error and should be reversed.

As stated by the examiner in the Office Action of August 7, 2008 at pages 2 and 3:

> "It would have been obvious to one of ordinary skill in the art to expect the compositions of Beerse et al to exhibit efficacy against bacteria with a log 3 reduction for 30 seconds because Beerse et al teach compositions that maintain a log 2 reduction against viruses for 30 minutes to an hour and the artisan of ordinary skill would expect the compositions of Beerse et al to exhibit a greater reduction in a shorter interval of time, in the absence of a showing to contrary. Moreover, the compositions of Beerse et al teach the same ingredients as claimed for the purpose of making an antimicrobial composition, wherein the artisan of ordinary skill would reasonably expect similar characteristics."

Appellants traverse this rejection because the compositions of the '186 patent are not equivalent to the compositions recited in the present claims.

1. Disclosure of the '186 Patent

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog *and* a metal salt ('186 patent abstract). In particular, the '186 patent, at column 3, lines 32-48 states:

> "The present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a benzoic acid analog;
> b) a safe and effective amount of a metal salt; and
> c) a dermatologically acceptable carrier for the acid and salt wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid.
>
> In another embodiment, the present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a metal-benzoic acid analog complex; and
> b) a dermatologically acceptable carrier for said complex wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid."

The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

> "Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent *in addition to* the aromatic carboxylic acid.

The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. The '186 patent, at column 47, lines 18-54 states, in part:

> "Furthermore, Applicants have found that compositions which contain a benzoic acid analog and a dermatologically acceptable carrier and which are essentially free of metal salts are also effective in providing residual anti-viral efficacy. Accordingly, Applicants have also found that such compositions are also effective in providing residual anti-viral efficacy. Applicants have also found that such compositions are useful for providing residual antibacterial efficacy... These methods of the present invention each comprise the step of topically applying a composition comprising a safe and effective amount of benzoic acid analog and a dermatologically acceptable carrier wherein said composition is essentially free of metal salts. As used herein, "essentially free" means that any metal salts are present in levels which are not detectable by means typically used in the arts to detect such compounds. Preferably, such compositions are free of metal salts and the benzoic acid analog is selected from the group consisting of benzoic acid, salicylic acid..."

The '186 patent contains one example (Example 21) that is free of a metal salt. However, the composition of this example also contains a total of 10 wt% of surfactants *and* 1.50% para-chloro-meta-xylenol (a second antimicrobial agent). See '186 patent, column 20, lines 34 through column 22, line 37, and particularly, column 21, lines 59 and 60. The

definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

The "dermatologically acceptable carrier" can comprise an alcohol solution (column 9, lines 32-43). The alcohol can be a monohydric alcohol, dihydric alcohol, and combinations thereof, with C_2-C_{18} monohydric alcohols being preferred alcohols (column 9, lines 44-54). The sole specific disclosure of dihydric alcohols in the '186 patent is in Examples 16-18, wherein dipropylene glycol is present in an amount of 8%, by weight. Examples 16-18 of the '186 patent each incorporate a metal salt.

2. Rejection of Claims 2, 3, 5, 6, 9, and 11-26 under 35 U.S.C. §103 As Being Obvious Over the '186 Patent

The present claims recite methods of reducing bacteria and virus populations on a surface by contacting the surface with a composition containing an aromatic carboxylic acid as the *sole* antimicrobial agent in the composition. The composition also (a) has a pH of about 2 to about 5.5, (b) contains a hydric solvent comprising dipropylene glycol in a sufficient amount to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* of 30 seconds contact, and (c) 0% to 0.2%, by weight, of a surfactant (i.e., is essentially free of a surfactant). As demonstrated below, the compositions used in the claimed methods demonstrate unexpected results for a composition lacking a second antimicrobial agent and/or a surfactant. The '186 patent fails to teach or suggest a composition that demonstrates this combination of features.

Appellants particularly direct the Board's attention to the examples in the specification. Specifically, Examples 1-3 show that pH is important to achieve efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic acid alone, i.e., in the absence of a hydric solvent, is not efficacious (Ex. 3). By "not efficacious", it is meant that the claimed log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact is not achieved, for example, see specification, page 22, lines 17-19 and page 25, lines 4-11. See the Declaration of Earl P. Seitz (Seitz Declaration, paragraph 17) filed on July 25, 2008 and provided in the Evidence Appendix herein at pages A6- A10.

Example 4 of the specification illustrates that a minimum amount of hydric solvent is required to achieve the claimed log reduction of at least 3. As stated in the specification at page 25:

> "It is envisioned that a minimum amount of hydric solvent is needed in a composition to provide an AEI of at least 3, and this minimum amount is related to the identity of the hydric solvent, solution pH, and aromatic carboxylic acid concentration. The minimum amount of hydric solvent can be readily determined for any composition by the test criteria described in this example."

The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims *exclude* the presence of a metal salt that is taught as essential in the '186 patent. In particular, the claims clearly recite that the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. However, the sole example of this embodiment, i.e., Example 21, differs in *three* substantial ways from the present composition. First, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50%, by weight, of the phenolic antimicrobial para-chloro-meta-xylenol (PCMX). See the '186 patent, column 20, line 34 through column 22, line 37, and especially column 21, lines 59-60. This *phenolic* antimicrobial agent is excluded from the present claims, i.e., it is *not* an aromatic carboxylic acid.

Second, a major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Third, Example 21 of the '186 patent also is free of a hydric solvent, which is a presently claimed ingredient in an amount of about 10% to about 40%, by weight, of the composition, and which is required to provide a composition capable of providing an at least log 3 reduction in *S. aureus* and/or *E. coli* after 30 seconds of contact. The sole example of

the '186 patent that is free of a metal salt therefore is completely different from a composition recited in the present claims.

The '186 patent also discloses that the carrier can be an alcohol solution, i.e., monohydric and/or dihydric alcohols. The preferred alcohols are monohydric C2-C18 alcohols, and the only specifically named alcohols are ethanol, isopropanol, n-propanol, butanol, and mixtures thereof. See '186 patent, column 9, lines 44-51. In contrast, the present claims recite at least 10% of a hydric solvent comprising dipropylene glycol as the hydric solvent. Claim 9 is limited to dipropylene glycol as the hydric solvent in an amount of at least 20%, by weight. Although the '186 patent discloses dipropylene glycol in Examples 16-18, these examples each include (a) a metal salt and (b) the dipropylene glycol is present in too low an amount (8%, by weight) to provide a claimed log reduction of at least 3, as claimed, in the absence of a metal salt. It also must be noted that Examples 16-18 of the '186 patent each include a metal salt, which is *excluded* from the present claims. The other '186 patent examples referred to and relied upon by the examiner, i.e., Examples 4, 12, 14, and 15 are free of a hydric solvent and contain a metal salt (which is excluded from the present claims).

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition *and* the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant *and* the composition contains an amount of hydric solvent sufficient to achieve a log reduction of at least 3 against *S. aureus* and *E. coli* after 30 seconds contact.

In the Office Action, the examiner provides responses to appellants' previous arguments, and many of the statements show a definite hindsight reconstruction of appellants' invention. In particular, the examiner has selected isolated teachings (i.e., ingredients or lack of ingredients) from different examples of the '186 patent to reconstruct appellants' claimed composition, while *neglecting* other features present in the *same* example relied upon by the examiner.

For example, the examiner states at page 3, paragraphs 3 and 4, of the Office Action:

> "3. Applicant argues that examples 16, 18, and 21 do not suggests [sic] the embodiments of Beerse et al that do not require metal acid complex and further some examples suggest antimicrobial agents.
>
> 4. The examiner contends that non-preferred embodiments are indicative of obviousness and that the teachings of Beerse et al suggest compositions that do not requires [sic] metal-salt complex and further include solvents as claimed in their requisite proportions."

Appellants are somewhat unsure of the meaning of paragraph 3, however, statements in paragraph 4 are incorrect. Examples 16 and 18 each contain cupric chloride as the metal salt and 8%, by weight, dipropylene glycol, which is *less than* the claimed minimum amount (i.e., 10%, by weight) of hydric solvent, i.e., do *not* "include solvents as claimed in their requisite proportions."

With respect to compositions that do not require a metal-salt complex, Example 21 is free of a metal-salt complex, but contains a high amount (1.5%, by weight) of PCMX to boost antimicrobial activity. Note that Examples 22-25 grouped with Example 21 *each* contain a metal salt, and each *omits* a second antimicrobial compound, because the metal salt provides the boost in antimicrobial activity. In addition, the '186 patent contains more than merely suggesting embodiments with a second antimicrobial agent. In fact, the '186 patent *specifically* teaches the presence of a second antimicrobial agent when a metal salt is omitted. The para-chloro-meta-xylenol of Example 21 of the '186 patent *is* an antimicrobial agent as specifically disclosed in the '186 patent at column 21, lines 59-60.

The examiner states at page 4, paragraphs 7 and 8, of the Office Action:

> "7. Applicant argues that Beerse et al teach that the addition of a metal-acid complex acts as an additional anti-microbial agent.
>
> 8. The examiner contends that applicant's claims are bound by the transitional phrase of "comprising [sic] which permits the inclusion of additional components not specified in the claim. Moreover, as stated by applicant", Beerse et al do not require metal-salts in all of the embodiments and specifically suggest that the embodiments free of metal salts are effective in provide [sic] residual anti-viral

> efficacy (col. 47, lines 18-55) Therefore, Beerse et al do not require a metal-salt component as suggested by applicant, and further applicant's claims permit the use of additional ingredients not specified."

The metal salt clearly acts as a second antimicrobial agent as set forth in the '186 patent at column 7, lines 60-65. With respect to the contention that the term "comprising" allows additional components to be included in the composition, it must be pointed out that the claims specifically are limited to the aromatic carboxylic acid being the *sole* antimicrobial agent. Additional antimicrobial agents are excluded, e.g.., the metal salts taught in the '186 patent as antimicrobial agents. See Evidence Appendix, Seitz Declaration, paragraphs 7, 12, and 15, and '186 patent, column 7, lines 60-65.

First, appellants did not state that the metal salt free embodiments of the '186 patent were efficacious. This is unknown to appellants. The sole embodiment is Example 21, which contains 10%, by weight, surfactant and 1.5%, by weight, of a second antimicrobial agent, i.e., PCMX. Furthermore, *no* efficacy data is provided in the '186 patent for Example 21. The '186 patent may contend that the second embodiment of the disclosure is efficacious in the absence of surfactant and/or second antimicrobial agent, but has neither demonstrated such efficacy nor exemplified any such efficacious composition.

With respect to the examiner's comment that the '186 patent does not require a metal salt component, the only example free of a metal salt has both (a) 1.5 wt % of a second phenolic antimicrobial agent and (b) 10 wt % of a surfactant. Although the '186 patent at column 47, lines 18-54 suggests use of a benzoic acid analog in the absence of a metal salt, the reference *explicitly* teaches that a second antimicrobial agent is present to add to the efficacy of the composition. Therefore, the phenolic antimicrobial agent present in Example 21 provides a boost in antimicrobial activity because the metal salt is absent. A presently claimed composition is *free* of both a second antimicrobial agent and a surfactant.

At pages 4 and 5 of the Office Action, paragraphs 9-11, the examiner further states:

> "9. Applicant argues that Beerse et al fail to suggest a surfactant having 0 to 0.2%; and 5 to 50% by weight of a hydric solvent.

> 10. The examiner respectfully disagrees and directs applicant's attention to column 27, lines 55-60, which teaches less than 10% by weight of surfactants are needed. With respect to the hydric solvent, Beerse et al. teach that said solvent is present in an amount from 0-95% (column 9, lines 44-55).
>
> 11. Applicant argues that example 21 does not comprise a metal-salt but also does suggest high levels of surfactants."

First, the '186 patent, at column 27, lines 56-59, actually states that *co-surfactants* are present at less than 10% by weight, i.e., "*Co-surfactants* consisting of *additional* anionic, nonionic, cationic, and amphoteric or zwitterionic surfactants can *also* be included, but typically comprise less than 10% by weight of the composition" (emphasis added). Prior to this limited disclosure, the '186 patent discloses innumerable surfactants at columns 22-27. The disclosure relating to co-surfactants relates to *additional* surfactants that *also* can be included with a surfactant. Accordingly, the examiner's reliance on column 27, lines 56-59 is misplaced. Moreover, the '186 patent fails to disclose a composition essentially (a) free of a surfactant, (b) free of a metal salt, *and* (c) free of a second antimicrobial agent. The examiner's reasoning is an example of hindsight reconstruction wherein an isolated statement is used to support a rejection without a consideration either of the claimed invention as a whole or the *complete* teachings of the reference.

In addition, Example 21 does not "suggest" high levels of surfactants. To be precise, Example 21 *explicitly teaches* 5.0% ammonium lauryl sulfate and 5.0% ammonium laureth-3 sulfate, or 10.0% total surfactant, by weight. This is *50* times the claimed maximum of surfactant.

At page 5 of the Office Action, paragraph 12, the examiner states:

> "The examiner contends that a reference does not need to teach each of the components in an example to be indicative of obviousness. The general teaching of Beerse et al states that metal –salt complex is not require [sic] to perform as suggested (col. 47, lines 18-55). Moreover, Beerse et al teach several embodiments that do not require surfactants (see examples 4, 12, 14-15, 16-18)."

The examiner appears to be saying that as long as individual ingredients of a composition can be found in a reference, then a claim can be found obvious. In looking at different embodiments of the '186 patent, the examiner is focusing on individual ingredients that may or may not be present, then adding the various ingredients together or deleting ingredients, to arrive at a conclusion of obviousness. The examiner has failed to clearly articulate *facts* as to the way the claimed invention "as a whole" would have been obvious to a person skilled in the art. In particular, the examiner has failed to consider the claimed invention as a whole, as opposed to its individual ingredients, and has failed to consider the unpredictability in the art, wherein changing the identity of an ingredient, or its actual or relative amount in a composition, can substantially influence antimicrobial efficacy. For example, see the examples in the present application. While the examiner appears to rationalize his conclusion of obviousness, the examiner does not articulate facts to support the asserted rationale. MPEP §2143.

The examiner is "cherry picking" individual ingredients from various portions and examples of the '186 patent without considering either the entire teaching of the embodiments in the '186 patent or the claimed invention as a whole. The sole explicit teaching of a composition that is free of a metal salt in the '186 patent (Example 21) contains 10 wt % of a surfactant and 1.5 wt. % of a second antimicrobial agent, *both* of which are excluded from the present claims. The examples relied upon by the examiner (i.e., 4, 12, and 14-18) *all* are free of a surfactant, but all *contain* a metal salt, which is excluded from the present claims.

In general, the examiner's reasoning also is inconsistent. To support exclusion of a metal salt, the examiner relies upon the limited general teachings of the '186 patent at column 47, lines 18-55, but neglects the specific teaching on Example 21. However, to support exclusion of a surfactant, the examiner neglects the extensive general teachings at *columns* 22-27 of the '186 patent to include a surfactant, but relies upon specific examples to exclude a surfactant. Overall, it is submitted that the '186 patent would *not* have *reasonably* suggested to a person skilled in the art to (a) exclude a second antimicrobial agent *and* (b) exclude surfactants *and* (c) exclude a metal salt *and* (d) include a sufficient amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact.

The examiner contends that testing against comparative examples is necessary to support patentability. At page 5 of the Office Action, paragraph 13, the examiner states:

> "13. The Declaration under 37 CFR 1.132 filed 7-25-2008 is insufficient to overcome the rejection of claims2-3 [sic], 5-6, 9, 11-26 based upon Beerse et al as set forth in the last Office action because: Declarant states an opinion of Beerse et al that is not supported by factual evidence which compares the closest prior art of record against the claimed invention."

However, appellants are not claiming an improvement over the '186 patent, but are claiming a method using an entirely different composition. The '186 patent contains no objective evidence of efficacy, but merely a definition of "residual antibacterial activity" at column 4, lines 22-39, and "Analytical Methods" at columns 44-46. However, even assuming *arguendo* that the '186 patent compositions are efficacious, comparing the present compositions to the '186 patent composition would serve little purpose. The compositions of the '186 patent arguably would be shown to be efficacious, and appellants already have shown that the claimed compositions are efficacious.

The present invention is a discovery that, contrary to the '186 patent, the claimed composition is efficacious in the *absence* of a metal salt, in the *absence* of a surfactant, and in the *absence* of any other second antimicrobial agent. The '186 patent fails to lead, or provide any apparent reason for, a person skilled in the art to make these multiple jumps in reasoning, and *then* include a sufficient amount of a claimed hydric solvent to provide the claimed log reduction of *S. aureus* and/or *E. coli* after 30 seconds contact.

More particularly, the present invention is demonstrated in the examples, wherein it is shown that an aromatic carboxylic acid or a hydric solvent *alone* does not provide a high antimicrobial efficacy, as claimed. Both the aromatic carboxylic acid and hydric solvent are needed to achieve a high antimicrobial efficacy, and a sufficient amount of the hydric solvent also is needed (see specification, Example 4).

In effect, appellants *have* provided comparative testing to the closest prior art. If one takes a composition from the '186 patent, and following the examiner's strained reasoning, then excludes the metal salt *and* a surfactant *and* any other second antimicrobial

agent, the resulting composition would be those tested in Examples 1, 3, and 4. These examples show that simply excluding one or more of these components does *not* provide a composition having the claimed efficacy. What is needed is a combination of aromatic carboxylic acid and a sufficient amount of hydric solvent, as claimed. It was appellants that made the inventive discovery of including a hydric solvent in the claimed amounts to provide a highly efficacious composition for use in the claimed method. This discovery is neither taught nor suggested in the '186 patent.

The presently claimed invention clearly exhibits unexpected results, even when the essential metal salt of the '186 patent is omitted. In particular, the present examples show an unexpectedly high antimicrobial efficacy when both an aromatic carboxylic *and* a claimed hydric solvent are present (see Examples 1, 4, 7, and 9). Comparative Examples 2 and 3 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy.

At page 6 of the Office Action, the "examiner contends that the general teaching of Beerse et al. states that the metal-salt complex is not require [sic] to perform as suggested". However, the only disclosure of the '186 patent supporting the statements at column 47, lines 18-54, is Example 21, wherein a *second* antimicrobial agent, i.e., PCMX, is utilized to enhance the antimicrobial activity of the benzoic acid analog. The substantial differences between Example 21 of the '186 patent and the present compositions are set forth above, and in the Seitz Declaration (Evidence Appendix, paragraphs 7-16), showing that the comparison between a composition of the '186 patent and a claimed composition would be meaningless.

The differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. In fact, the '186 patent fails to support a *prima facie* obviousness rejection over the present claims. Simply put, the '186 patent provides no apparent reason to modify the '186 patent as suggested by the examiner with any reasonable expectation of providing an efficacious antibacterial method. The '186 patent stresses the necessity of either including a metal salt or using another second antimicrobial agent in the composition in order to achieve an enhanced antimicrobial action. For example, the '186 patent includes 42 examples, of which 41 contain a metal salt as an

antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant *and* is lacking a hydric solvent *and* contains a second antimicrobial agent. The '186 patent fails to teach or suggest a composition that (a) omits a metal salt and other additional antimicrobial agents, *and* (b) is essentially free of a surfactant, *and* (c) includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not have had any apparent reason to omit a metal salt *and* omit a surfactant *and* include a claimed hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

To establish a *prima facie* case of obviousness, *all three* requirements recited in MPEP §2143 must be satisfied: (1) the prior art reference or combination of references must teach or suggest *all the limitations* of the claims to those of ordinary skill in the art. See *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."); (2) the prior art relied upon must contain some suggestion or incentive, coupled with knowledge generally available in the art at the time of the invention, that would have motivated those of ordinary skill in the art to modify a reference or combine the references. See, *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385, 58 USPQ2d 1286, 1293 (Fed. Cir. 2001) ("in holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in a way that would produce the claimed invention."); *and* (3) the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

In the present application, the '186 patent fails to teach or suggest all the limitations of the claims to those of ordinary skill in the art, i.e., an aromatic carboxylic acid as the sole antimicrobial agent, the claimed minimum amount of dipropylene glycol, and the claimed amount of surfactant.

The '186 patent also fails to provide an apparent reason to modify the teachings of the reference and arrive at the present invention. The '186 patent has a limited disclosure that a metal ion can be excluded from the composition, but the reference fails to

teach that an aromatic carboxylic acid can be used as the sole antimicrobial agent. The '186 patent explicitly teaches using a second antimicrobial agent when the metal ion is excluded. The '186 patent also teaches using a high amount of surfactant in the absence of a metal ion, and fails to teach dipropylene glycol in the absence of a metal ion. Also see Seitz Declaration, Evidence Appendix, paragraphs 8-18.

The proposed modifications of the '186 patent to arrive at the present invention also would not have a reasonable expectation of success, as seen through the eye of a person skilled in the art. See Seitz Declaration, Evidence Appendix, paragraph 18.

The '186 patent therefore fails to meet the criteria set forth as MPEP §2143, and accordingly, a *prima facie* case of obviousness has not been made and the rejection should be withdrawn.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be reversed.

IX. CONCLUSION

In view of the foregoing remarks, appellants respectfully request that the Board reverse the final rejection of claims 2, 3, 5, 6, 9, and 11-26, and that all pending claims should be allowed.

Dated: February 9, 2009

Respectfully submitted,

By _____

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CLAIMS APPENDIX

Claims on Appeal in Application Serial No. 10/720,862

1. (Cancelled)

2. (Previously presented) The method of claim 17 comprising about 0.1% to about 5%, by weight, of the aromatic carboxylic acid.

3. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid has a pKa of about 2.5 to about 7.

4. (Cancelled)

5. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof

6. (Previously presented) The method of claim 17 wherein the antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof.

7. (Cancelled)

8. (Cancelled)

9. (Previously presented) The method of claim 17 wherein the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol.

10. (Cancelled)

11. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof.

12. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof.

13. (Previously presented) The method of claim 17 wherein the pH-adjusting compound is present in an amount of about 1% to about 5%, by weight, of the composition.

14. (Previously presented) The method of claim 17 having a pH of about 2 to about 5.

15. (Previously presented) The method of claim 17 wherein the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof.

16. (Previously presented) The method of claim 17 comprising:

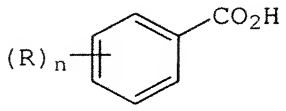
(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5.

17. (Previously presented) A method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

18. (Original) The method of claim 17 wherein the composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*.

19. (Original) The method of claim 17 wherein a log reduction of at least 3 is achieved in a viral population.

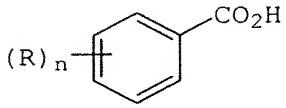
20. (Original) The method of claim 19 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

21. (Original) The method of claim 17 wherein the surface is a skin of a mammal.

22. (Previously presented) A method of reducing a viral population on a surface comprising contacting the surface with a composition of for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

23. (Original) The method of claim 22 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

24. (Original) The method of claim 22 wherein the surface is a skin of a mammal.

25. (Previously presented) The method of claim 16 wherein the antimicrobial carboxylic acid comprises salicyclic acid.

26. (Previously presented) The method of claim 16 wherein the composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof.

EVIDENCE APPENDIX

Declaration of Earl P. Seitz under 37 C.F.R. §1.132, filed July 25, 2008.

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 — Confirmation No.: 5172

Filed: November 24, 2003 — Art Unit: 1751

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent — Examiner: N. Ogden

DECLARATION OF EARL P. SEITZ UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

NOW COMES EARL P. SEITZ, Declarant herein, and states as follows:

1. I am a coinventor of the invention disclosed and claimed in the above-identified patent application.

2. I have been employed by The Dial Corporation (Dial), Scottsdale, Arizona, since 1978. I was a Research Manager of various technology and product development groups at Dial from 1980 to 1994. I am presently a Research Fellow at Dial, and have held this position since 1994. I am engaged in the research and development of personal care products, including compositions containing topically active components. In 2001, I was awarded Dial's R&D's highest technical award, the Robert E. Casely Award for Excellence in Innovation.

3. I received a Ph.D. in organic chemistry from Oregon State University, Corvallis, Oregon (1977), and a B.S. in chemistry from Texas Christian University, Fort Worth, Texas (1968). I also served in the U S. Navy from 1969-1972, and held a post-doctoral position at The University of Wisconsin, Madison, WI in 1977 and 1978.

4. I have conducted research in the fields of skin cleansers and related surfactant-based compositions, including topically active and antibacterial compositions. I am a named inventor on seven U.S. patents involving technology disclosed in the above-identified patent application.

5. I have read and understand the Office Action dated March 28, 2008, which was issued in connection with U.S. Patent Application Serial No. 10/720,862. I also have read and understand the following patent cited by the examiner in U.S.S.N. 10/720,862: Beerse et al. U.S. Patent No. 6,294,186 ('186)).

6. Claims 2, 3, 5, 6, 9, and 11-26, all of the claims in the application, have been rejected as being obvious over the '186 patent. The basis of this rejection is that a skilled person would expect the claimed compositions to exhibit a similar antibacterial activity to compositions of the '186 patent because the '186 patent teaches the "same" ingredients. Contrary to the examiner's assertion, the compositions disclosed in the '186 patent are substantially different from the compositions recited in the presently-claimed methods.

7. The '186 patent describes and claims compositions comprising an antimicrobial agent. The title of the specification of the '186 patent is "Antimicrobial Compositions Comprising a Benzoic Acid Analogue and a Metal Salt". The '186 patent explicitly teaches that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states that "[W]ithout being limited by theory, it is believed that the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide the synergistic immediate and residual anti-viral and anti-bacterial efficacy to surfaces to which such compositions are applied" ('186 patent, column 7, lines 60-65).

8. The '186 patent contains 42 examples. Of these 42 examples, 41 contain a metal salt as an antimicrobial agent in addition to the aromatic carboxylic acid.

9. The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. This embodiment is identified by one sole example, namely

Example 21 in the '186 patent. However, the composition of this example also contains a total of 10 weight per cent of surfactants and 1.50% para-chloro-meta-xylenol, which is a second antimicrobial agent.

10. With regard to a hydric solvent, the '186 patent recites that a carrier for the disclosed composition can be an alcohol (see for example, column 9, lines 33-54 of the '186 patent). The sole disclosure in the '186 patent of dipropylene glycol, as claimed in the present invention, is in Examples 16 to 18. In these examples, the amount of dipropylene glycol is 8% by weight. Examples 16 to 18 of the '186 patent also include a metal salt, which is excluded from the present claims.

11. As stated above, the presently claimed composition includes aromatic carboxylic acid as the *sole* antimicrobial agent, an amount of hydric solvent, and 0% of 0.2% by weight of a surfactant. Having read the '186 patent, I can find no disclosure or suggestion that would lead a person skilled in the art to the presently claimed composition.

12. Moreover, the '186 patent *explicitly* teaches that the metal salt is an essential ingredient in the first embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims exclude the presence of a metal salt that is taught as essential in the '186 patent.

13. In the second embodiment of the '186 patent, a metal salt is absent. However, the sole example of this embodiment, i.e., Example 21, differs in three substantial ways from the presently claimed composition. Firstly, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50% by weight of the additional antimicrobial agent para-chloro-meta-xylenol (PCMX), i.e., a phenolic antimicrobial agent. This antimicrobial agent is excluded from the claims of the patent application in suit, i.e., it is not an aromatic carboxylic acid.

14. Secondly, Example 21 in the '186 patent contains a high amount of surfactant (10 weight per cent). In contrast, the present claims recite a composition having 0% to 0.2% by weight of a surfactant. Thirdly, Example 21 of the '186 patent is free of a hydric solvent, which is required in the claims of the application.

15. In summary, it is my opinion that the '186 patent teaches that a metal salt is essential to provide a synergistic effect, as a second microbial agent together with a first aromatic antimicrobial agent. As a skilled person, when reading this document I am told that the metal salt is essential for performing the invention of the '186 patent. In view of the teaching of the '186 patent that the metal salt provides a synergistic effect, it would be my belief on reading this document that omitting the metal salt would cause the invention of the '186 patent to fail, i.e., not provide sufficient antimicrobial action. Further, if a metal salt is excluded, the '186 patent then teaches me that a different second antimicrobial agent, e.g., PCMX, must be present to be efficacious, as in Example 21 of the '186 patent.

16. However, the disclosure of the '186 patent is inconsistent and has one example in which the metal salt is omitted, despite the fact that the document appears to be geared toward compositions containing a metal salt. However, this embodiment is substantially different from the composition of the present claims and it is meaningless to compare Example 21 with the compositions of the invention, given that the example is so different from the claimed invention. Moreover, Example 21 also contains a further antimicrobial agent to provide an enhanced antimicrobial effect in view of the absence of a metal salt.

17. The efficacy of the present invention is demonstrated by the examples in the specification. Examples 1-3 show that pH is important to enhance efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic alone, i.e., in the absence of a hydric solvent, is not efficacious.[1] Example 4 shows that a minimum amount of hydric solvent is required to achieve a log reduction of at least 3, as claimed. Example 9 shows that the method and composition are highly effective in reducing viral populations.

18. These efficacious results are achieved by using compositions free of a metal salt, essentially free of a surfactant, and containing an aromatic carboxylic acid as the sole antimicrobial agent in the composition. A person skilled in the art, after reading the '186 patent, would not have considered making any of these modifications, let alone all three, and still expect to provide a log reduction against *S. aureus* and/or *E. coli* of at least three.

[1] Efficacy is measured as a log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact.

19. The compositions claimed in the present application require a sole antimicrobial agent and is essentially free of an optional surfactant. The inventors of the present application have determined using their inventive skill that an antimicrobial composition can be effective using a sole antimicrobial agent without the mandatory metal salt of the '186 patent (to provide synergistic activity) or a second antimicrobial agent. Despite not having *either of* these ingredients, the claimed compositions are surprisingly effective.

20. The use of a single antimicrobial agent in the present application is an advantage, not least in terms of the resulting commercial product and ease of production of the product.

21. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Dated: 24 JULY, 2008

Earl P. Seitz

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 | Confirmation No.: 5172

Filed: November 24, 2003 | Art Unit: 1796

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent | Examiner: Necholus Ogden, Jr.

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

This Appeal Brief is submitted in triplicate to support the Notice of Appeal filed in this application on December 8, 2008. This Appeal Brief is accompanied by the fee for filing an Appeal Brief under 37 C.F.R. §1.17(b). Accordingly, this Appeal Brief is timely filed and no further fees are believed due.

Any additional required fee may be charged, or any overpayment credited, to Deposit Account No. 13-2855.

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II. REAL PARTY IN INTEREST

The real party in interest in this appeal is The Dial Corporation (Dial), Scottsdale, Arizona, the assignee of the entire right, title, and interest to the above-identified patent application. The assignment was recorded in the United States Patent and Trademark Office ("USPTO") at Reel 15159, Frame 0142 on April 1, 2004, which constitutes the entire chain of title from the inventors to Dial.

III. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to appellants, appellants' legal representative, or the assignee which will directly affect or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

IV. STATUS OF CLAIMS

A. HISTORY

This application was originally field with claims 1-24. Claims 25 and 26 were added to the application during prosecution.

B. CURRENT STATUS OF CLAIMS

Claims cancelled: 1, 4, 7, 8, and 10.

Claims withdrawn from consideration but not cancelled: None.

Claims pending: 2, 3, 5, 6, 9, and 11-26.

Claims allowed: None.

Claims rejected: 2, 3, 5, 6, 9, and 11-26.

C. CLAIMS ON APPEAL

The claims on appeal are claims 2, 3, 5, 6, 9, and 11-26.

V. STATUS OF AMENDMENTS

Appellants filed a Response to Office Action and a Request for Continued Examination on July 25, 2008. The response and claim amendments therein were entered. Accordingly, appellants understand that the current form of the claims are represented by the Response to Office Action of July 25, 2008, as reproduced in the Claims Appendix below.

VI. SUMMARY OF CLAIMED SUBJECT MATTER

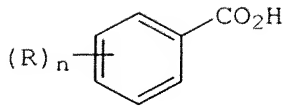
The present invention is directed to a method of reducing a bacteria and/or a virus population on a surface by contacting the surface with an antimicrobial composition. After 30 seconds of contact with the composition, the surface demonstrates a log reduction of at least 3 against *S. aureus* and/or *E. coli*. The method also demonstrates antiviral activity. The surface can be animate or inanimate.

Important features of the claimed composition are: (a) an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition, (b) the composition contains 0% to 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant, *and* (c) the composition contains a hydric solvent comprising dipropylene glycol. The claimed compositions demonstrate unexpected antibacterial and antiviral results for a composition lacking a second antimicrobial agent and a surfactant. In particular, the examples in the specification show an unexpectedly high antimicrobial efficacy when *both* an aromatic carboxylic as the sole antimicrobial agent *and* a claimed hydric solvent are present (see Examples 1, 3, 4, 7, and 9). Comparative Examples 2 and 8 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy. The examples also show that a minimum amount of hydric solvent is required in the composition to obtain a log 3 reduction in bacterial populations, as recited. Specification, page 25, lines 6-11.

The above features of the present invention are clearly set forth in independent claims 17 and 22, wherein a surface is contacted with an antimicrobial solution for 30 seconds to reduce bacteria population (claim 17) or a viral population (claim 22).

More particularly, claim 17 recites a method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 6, line 29 through page 7, line 12; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 2, 3, 5, 6, 9, 11-16, 18-21, 25, and 26 depend from claim 17.

Claim 2 recites that the antimicrobial composition comprises about 0.1% to about 5%, by weight, of the aromatic carboxylic acid. Specification, page 10, lines 9-12.

Claim 3 recites that the aromatic carboxylic acid of the antimicrobial composition has a pKa of about 2.5 to about 7. Specification, page 11, line 1 through page 12, line 8.

Claim 5 recites that the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof. Specification, page 11, line

15 through 12, line 8. Claim 6 recites that antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof. Specification, page 11, line 15 through page 12, line 8.

Claim 9 recites that the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol. Specification, page 24, lines 13-20 and page 25, Table of Example 4.

Claim 11 recites that the antimicrobial composition comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof. Specification, page 13, lines 15-22.

Claim 12 recites that the antimicrobial composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof. Specification, page 13, lines 15-22.

Claim 13 recites that the pH-adjusting compound is present in the antimicrobial composition in an amount of about 1% to about 5%, by weight, of the composition. Specification, page 13, line 29 through page 14, line 2.

Claim 14 recites that the antimicrobial composition has a pH of about 2 to about 5. Specification, page 13, lines 24-29.

Claim 15 recites that the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof. Specification, page 14, lines 14-21.

Claim 16 recites that the antimicrobial composition comprises

(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5. Specification, page 10, lines 12-15; page 12, lines 18-21; and page 13, lines 24-29.

Claim 18 recites that the antimicrobial composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*. Specification, page 6, line 29 through page 7, line 12.

Claim 19 recites that the antimicrobial composition achieves a log reduction of at least 3 in a viral population. Specification, page 7, lines 13-17.

Claim 20 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 21 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 16-19; and page 28, lines 19-28.

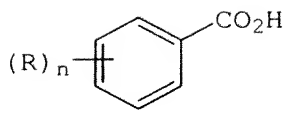
Claim 25, which depends from claim 16, recites that the antimicrobial carboxylic acid comprises salicylic acid. Specification, page 12, lines 4-8 and page 22, Example 1, lines 5-23.

Claim 26, which also depends from claim 16, recites that the antimicrobial composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof. Specification, page 13, lines 13-22.

Independent claim 22 recites a method of reducing a viral population on a surface comprising contacting the surface with a composition for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

Specification, page 6, lines 3-13 and lines 25-28; page 7, lines 13-17; page 9, lines 4-13 and lines 24-30; page 11, lines 6-14; and page 12, lines 18-21.

Claims 23 and 24 depend from claim 22.

Claim 23 recites that the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof. Specification, page 22, lines 1-4.

Claim 24 recites that the surface contacted with the antimicrobial composition is the skin of a mammal. Specification, page 7, line 18 through page 8, line 5; page 9, lines 10-19; and page 28, lines 19-28.

VII. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 2, 3, 5, 6, 9, and 11-26 would have been obvious under 35 U.S.C. §103 over Beerse et al. U.S. Patent No. 6,294,186 ('186).

For purposes of the issues on appeal, claims 2, 3, 5, 6, 9, and 11-26 are grouped and argued together.

VIII. ARGUMENT

A. INTRODUCTION

Appellants submit that the rejection issued in the final Office Action is in error, and that the present application is in condition for allowance. Appellants respectfully request the Board to review and reverse the rejection issued in the final Office Action.

B. PROPER BASIS FOR A §103(a) OBVIOUSNESS REJECTION

A determination that a claimed invention would have been obvious under §103(a) is a legal conclusion involving four factual inquiries: (1) the scope and content of the prior art; (2) the differences between the claimed invention and the prior art; (2) the differences between the claimed invention and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of non-obviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). Secondary considerations of non-obviousness include factors such as commercial success, long-felt but unresolved needs, the failure of others, and/or unexpected results achieved by the claimed invention. *Id.* Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the claimed subject matter pertains, who is presumed to have all prior art references in the field of the invention available to him/her. In *re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998). Furthermore, obviousness must be determined as of the time the invention was made and in view of the state of the art that existed at that time. *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1050-51 (Fed. Cir. 1988).

The Patent Office must clearly articulate facts and reasons why the claimed invention "as a whole" would have been obvious to a hypothetical person having ordinary skill in the art at least as of the claimed invention's effective filing date. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007) (citing with approval In *re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")); see also MPEP §2143 ("The key to supporting any rejection under 35 U.S.C. §103 is the clear articulation of reason(s) why the claimed invention would have been obvious.").

To reach a proper determination under 35 U.S.C. §103(a), the examiner must step backward in time and into the shoes worn by the hypothetical "person of ordinary skill in the art" when the invention was unknown and just before it was made. In view of all factual information, the examiner must then make a determination whether the claimed invention "as a whole" would have been obvious at that time to that person. Knowledge of appellants' disclosure must be put aside in reaching this determination, yet kept in mind in order to determine the "differences," conduct the search, and evaluate the "subject matter as a whole" of the invention. The tendency to resort to "hindsight" based upon appellants' disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the *facts* gleaned from the prior art. MPEP §2142.

Furthermore, to establish a *prima facie* case of obviousness, the examiner must satisfy three requirements. First, as the U.S. Supreme Court recently held in *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was *an apparent reason* to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to *identify* a *reason that would have prompted a person of ordinary skill in the relevant field to combine the elements* in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (emphasis added, *KSR*, *supra*). Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. In *re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

As recently articulated by the Court of Appeals for the Federal Circuit in *Ortho-McNeil Pharmaceutical Inc. v. Mylan Laboratories Inc.*, 86 USPQ 2d, 1196, 1201-2 (Fed. Cir. 2008):

> "As this court has explained, however, a flexible TSM test remains the primary guarantee against a non-statutory hindsight analysis such as occurred in this case. *In re Translogic Tech., Inc.* 504 F.3d 1249, 1257 [84 USPQ 2d 1929] (Fed. Cir. 2007) ("[A]s the Supreme Court suggests, a flexible approach to the TSM test prevents hindsight and focuses on evidence before the time of invention.)."

Once the Patent Office properly sets forth a prima facie case of obviousness, the burden shifts to the appellants to come forward with evidence and/or arguments supporting patentability. *See In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is merely a showing of facts supporting the opposite conclusion. *In re Piasecki*, 745 F.2d 1468,1472 (Fed. Cir. 1984). Evidence rebutting a prima facie case of obviousness can include: (a) "evidence of unexpected results," *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 1369 (Fed. Cir. 2007); (b) "evidence that the prior art teaches away from the claimed invention in any material respect," *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003); and, (c) evidence of secondary considerations, such as commercial success or long-felt yet unmet needs, *WMS Gaming, Inc. v. International Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999). The Patent Office must always consider such evidence supporting patentability. *See, e.g., In re Sullivan*, 498 F.3d 1345, 1352-53 (Fed. Cir. 2007) (reversing a Patent Office decision of obviousness because the Patent Office failed to consider the applicants' evidence rebutting a prima facie case of obviousness). If the Patent Office determines that such evidence is not compelling or is insufficient, then the Patent Office should specifically set forth the facts and reasoning supporting that determination. MPEP §2145 (8th Ed., Rev. 6, Sept. 2007).

C. REJECTION OF CLAIMS 2, 3, 5, 6, 9, AND 11-26 UNDER 35 U.S.C. §103 AS BEING OBVIOUS OVER THE '186 PATENT

Claims 2, 3, 5, 6, 9, and 11-26 stand rejected under 35 U.S.C. §103 as being obvious over the '186 patent. The examiner contends that the '186 patent renders the claimed methods obvious because the cited reference teaches compositions containing the same ingredients as the claimed compositions, and therefore are expected to provide similar characteristics. It is submitted that this rejection is in error and should be reversed.

As stated by the examiner in the Office Action of August 7, 2008 at pages 2 and 3:

> "It would have been obvious to one of ordinary skill in the art to expect the compositions of Beerse et al to exhibit efficacy against bacteria with a log 3 reduction for 30 seconds because Beerse et al teach compositions that maintain a log 2 reduction against viruses for 30 minutes to an hour and the artisan of ordinary skill would expect the compositions of Beerse et al to exhibit a greater reduction in a shorter interval of time, in the absence of a showing to contrary. Moreover, the compositions of Beerse et al teach the same ingredients as claimed for the purpose of making an antimicrobial composition, wherein the artisan of ordinary skill would reasonably expect similar characteristics."

Appellants traverse this rejection because the compositions of the '186 patent are not equivalent to the compositions recited in the present claims.

1. Disclosure of the '186 Patent

The '186 patent primarily teaches an antimicrobial composition containing a benzoic acid analog *and* a metal salt ('186 patent abstract). In particular, the '186 patent, at column 3, lines 32-48 states:

> "The present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a benzoic acid analog;
> b) a safe and effective amount of a metal salt; and
> c) a dermatologically acceptable carrier for the acid and salt wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid.
>
> In another embodiment, the present invention relates to an antimicrobial composition comprising:
> a) a safe and effective amount of a metal-benzoic acid analog complex; and
> b) a dermatologically acceptable carrier for said complex wherein said composition has a pH of from about 1 to about 7 and is substantially free of para-amino salicylic acid."

The '186 patent further teaches, explicitly, that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states, at column 7, lines 60-65:

> "Without being limited by theory, it is believed that in the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide a synergistic immediate and residual anti-viral and antibacterial efficacy to surfaces to which such compositions are applied."

The '186 patent also contains 42 examples. Of these examples, 41 contain a metal salt as an antimicrobial agent *in addition to* the aromatic carboxylic acid.

The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. The '186 patent, at column 47, lines 18-54 states, in part:

> "Furthermore, Applicants have found that compositions which contain a benzoic acid analog and a dermatologically acceptable carrier and which are essentially free of metal salts are also effective in providing residual anti-viral efficacy. Accordingly, Applicants have also found that such compositions are also effective in providing residual anti-viral efficacy. Applicants have also found that such compositions are useful for providing residual antibacterial efficacy... These methods of the present invention each comprise the step of topically applying a composition comprising a safe and effective amount of benzoic acid analog and a dermatologically acceptable carrier wherein said composition is essentially free of metal salts. As used herein, "essentially free" means that any metal salts are present in levels which are not detectable by means typically used in the arts to detect such compounds. Preferably, such compositions are free of metal salts and the benzoic acid analog is selected from the group consisting of benzoic acid, salicylic acid..."

The '186 patent contains one example (Example 21) that is free of a metal salt. However, the composition of this example also contains a total of 10 wt% of surfactants *and* 1.50% para-chloro-meta-xylenol (a second antimicrobial agent). See '186 patent, column 20, lines 34 through column 22, line 37, and particularly, column 21, lines 59 and 60. The

definition of dermatologically effective carriers in the '186 patent includes surfactants of the type disclosed in Example 21. See '186 patent, column 8, line 49 through column 9, line 3.

The "dermatologically acceptable carrier" can comprise an alcohol solution (column 9, lines 32-43). The alcohol can be a monohydric alcohol, dihydric alcohol, and combinations thereof, with C_2-C_{18} monohydric alcohols being preferred alcohols (column 9, lines 44-54). The sole specific disclosure of dihydric alcohols in the '186 patent is in Examples 16-18, wherein dipropylene glycol is present in an amount of 8%, by weight. Examples 16-18 of the '186 patent each incorporate a metal salt.

2. Rejection of Claims 2, 3, 5, 6, 9, and 11-26 under 35 U.S.C. §103 As Being Obvious Over the '186 Patent

The present claims recite methods of reducing bacteria and virus populations on a surface by contacting the surface with a composition containing an aromatic carboxylic acid as the *sole* antimicrobial agent in the composition. The composition also (a) has a pH of about 2 to about 5.5, (b) contains a hydric solvent comprising dipropylene glycol in a sufficient amount to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* of 30 seconds contact, and (c) 0% to 0.2%, by weight, of a surfactant (i.e., is essentially free of a surfactant). As demonstrated below, the compositions used in the claimed methods demonstrate unexpected results for a composition lacking a second antimicrobial agent and/or a surfactant. The '186 patent fails to teach or suggest a composition that demonstrates this combination of features.

Appellants particularly direct the Board's attention to the examples in the specification. Specifically, Examples 1-3 show that pH is important to achieve efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic acid alone, i.e., in the absence of a hydric solvent, is not efficacious (Ex. 3). By "not efficacious", it is meant that the claimed log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact is not achieved, for example, see specification, page 22, lines 17-19 and page 25, lines 4-11. See the Declaration of Earl P. Seitz (Seitz Declaration, paragraph 17) filed on July 25, 2008 and provided in the Evidence Appendix herein at pages A6- A10.

Example 4 of the specification illustrates that a minimum amount of hydric solvent is required to achieve the claimed log reduction of at least 3. As stated in the specification at page 25:

> "It is envisioned that a minimum amount of hydric solvent is needed in a composition to provide an AEI of at least 3, and this minimum amount is related to the identity of the hydric solvent, solution pH, and aromatic carboxylic acid concentration. The minimum amount of hydric solvent can be readily determined for any composition by the test criteria described in this example."

The '186 patent explicitly teaches that the metal salt is an essential ingredient in one embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims *exclude* the presence of a metal salt that is taught as essential in the '186 patent. In particular, the claims clearly recite that the aromatic carboxylic acid is the *sole* antimicrobial agent in the composition.

In the second embodiment disclosed in the '186 patent, a metal salt is absent from a composition containing a benzoic acid analog and a dermatologically acceptable carrier. However, the sole example of this embodiment, i.e., Example 21, differs in *three* substantial ways from the present composition. First, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50%, by weight, of the phenolic antimicrobial para-chloro-meta-xylenol (PCMX). See the '186 patent, column 20, line 34 through column 22, line 37, and especially column 21, lines 59-60. This *phenolic* antimicrobial agent is excluded from the present claims, i.e., it is *not* an aromatic carboxylic acid.

Second, a major carrier exemplified in the '186 patent in connection with this embodiment is a high (10 wt%) amount of surfactant (see '186 patent, Example 21). In contrast, the present claims recite a composition that contains 0% to about 0.2%, by weight, of a composition. Third, Example 21 of the '186 patent also is free of a hydric solvent, which is a presently claimed ingredient in an amount of about 10% to about 40%, by weight, of the composition, and which is required to provide a composition capable of providing an at least log 3 reduction in *S. aureus* and/or *E. coli* after 30 seconds of contact. The sole example of

the '186 patent that is free of a metal salt therefore is completely different from a composition recited in the present claims.

The '186 patent also discloses that the carrier can be an alcohol solution, i.e., monohydric and/or dihydric alcohols. The preferred alcohols are monohydric C2-C18 alcohols, and the only specifically named alcohols are ethanol, isopropanol, n-propanol, butanol, and mixtures thereof. See '186 patent, column 9, lines 44-51. In contrast, the present claims recite at least 10% of a hydric solvent comprising dipropylene glycol as the hydric solvent. Claim 9 is limited to dipropylene glycol as the hydric solvent in an amount of at least 20%, by weight. Although the '186 patent discloses dipropylene glycol in Examples 16-18, these examples each include (a) a metal salt and (b) the dipropylene glycol is present in too low an amount (8%, by weight) to provide a claimed log reduction of at least 3, as claimed, in the absence of a metal salt. It also must be noted that Examples 16-18 of the '186 patent each include a metal salt, which is *excluded* from the present claims. The other '186 patent examples referred to and relied upon by the examiner, i.e., Examples 4, 12, 14, and 15 are free of a hydric solvent and contain a metal salt (which is excluded from the present claims).

In contrast to the teachings of the '186 patent, the present claims recite a composition wherein an aromatic carboxylic acid is the *sole* antimicrobial agent in the composition *and* the composition contains 0% to about 0.2%, by weight, of a surfactant, i.e., is essentially free of a surfactant *and* the composition contains an amount of hydric solvent sufficient to achieve a log reduction of at least 3 against *S. aureus* and *E. coli* after 30 seconds contact.

In the Office Action, the examiner provides responses to appellants' previous arguments, and many of the statements show a definite hindsight reconstruction of appellants' invention. In particular, the examiner has selected isolated teachings (i.e., ingredients or lack of ingredients) from different examples of the '186 patent to reconstruct appellants' claimed composition, while *neglecting* other features present in the *same* example relied upon by the examiner.

For example, the examiner states at page 3, paragraphs 3 and 4, of the Office Action:

"3. Applicant argues that examples 16, 18, and 21 do not suggests [sic] the embodiments of Beerse et al that do not require metal acid complex and further some examples suggest antimicrobial agents.

4. The examiner contends that non-preferred embodiments are indicative of obviousness and that the teachings of Beerse et al suggest compositions that do not requires [sic] metal-salt complex and further include solvents as claimed in their requisite proportions."

Appellants are somewhat unsure of the meaning of paragraph 3, however, statements in paragraph 4 are incorrect. Examples 16 and 18 each contain cupric chloride as the metal salt and 8%, by weight, dipropylene glycol, which is *less than* the claimed minimum amount (i.e., 10%, by weight) of hydric solvent, i.e., do *not* "include solvents as claimed in their requisite proportions."

With respect to compositions that do not require a metal-salt complex, Example 21 is free of a metal-salt complex, but contains a high amount (1.5%, by weight) of PCMX to boost antimicrobial activity. Note that Examples 22-25 grouped with Example 21 *each* contain a metal salt, and each *omits* a second antimicrobial compound, because the metal salt provides the boost in antimicrobial activity. In addition, the '186 patent contains more than merely suggesting embodiments with a second antimicrobial agent. In fact, the '186 patent *specifically* teaches the presence of a second antimicrobial agent when a metal salt is omitted. The para-chloro-meta-xylenol of Example 21 of the '186 patent *is* an antimicrobial agent as specifically disclosed in the '186 patent at column 21, lines 59-60.

The examiner states at page 4, paragraphs 7 and 8, of the Office Action:

"7. Applicant argues that Beerse et al teach that the addition of a metal-acid complex acts as an additional anti-microbial agent.

8. The examiner contends that applicant's claims are bound by the transitional phrase of "comprising [sic] which permits the inclusion of additional components not specified in the claim. Moreover, as stated by applicant", Beerse et al do not require metal-salts in all of the embodiments and specifically suggest that the embodiments free of metal salts are effective in provide [sic] residual anti-viral

> efficacy (col. 47, lines 18-55) Therefore, Beerse et al do not require a metal-salt component as suggested by applicant, and further applicant's claims permit the use of additional ingredients not specified."

The metal salt clearly acts as a second antimicrobial agent as set forth in the '186 patent at column 7, lines 60-65. With respect to the contention that the term "comprising" allows additional components to be included in the composition, it must be pointed out that the claims specifically are limited to the aromatic carboxylic acid being the *sole* antimicrobial agent. Additional antimicrobial agents are excluded, e.g.., the metal salts taught in the '186 patent as antimicrobial agents. See Evidence Appendix, Seitz Declaration, paragraphs 7, 12, and 15, and '186 patent, column 7, lines 60-65.

First, appellants did not state that the metal salt free embodiments of the '186 patent were efficacious. This is unknown to appellants. The sole embodiment is Example 21, which contains 10%, by weight, surfactant and 1.5%, by weight, of a second antimicrobial agent, i.e., PCMX. Furthermore, *no* efficacy data is provided in the '186 patent for Example 21. The '186 patent may contend that the second embodiment of the disclosure is efficacious in the absence of surfactant and/or second antimicrobial agent, but has neither demonstrated such efficacy nor exemplified any such efficacious composition.

With respect to the examiner's comment that the '186 patent does not require a metal salt component, the only example free of a metal salt has both (a) 1.5 wt % of a second phenolic antimicrobial agent and (b) 10 wt % of a surfactant. Although the '186 patent at column 47, lines 18-54 suggests use of a benzoic acid analog in the absence of a metal salt, the reference *explicitly* teaches that a second antimicrobial agent is present to add to the efficacy of the composition. Therefore, the phenolic antimicrobial agent present in Example 21 provides a boost in antimicrobial activity because the metal salt is absent. A presently claimed composition is *free* of both a second antimicrobial agent and a surfactant.

At pages 4 and 5 of the Office Action, paragraphs 9-11, the examiner further states:

> "9. Applicant argues that Beerse et al fail to suggest a surfactant having 0 to 0.2%; and 5 to 50% by weight of a hydric solvent.

> 10. The examiner respectfully disagrees and directs applicant's attention to column 27, lines 55-60, which teaches less than 10% by weight of surfactants are needed. With respect to the hydric solvent, Beerse et al. teach that said solvent is present in an amount from 0-95% (column 9, lines 44-55).
>
> 11. Applicant argues that example 21 does not comprise a metal-salt but also does suggest high levels of surfactants."

First, the '186 patent, at column 27, lines 56-59, actually states that *co-surfactants* are present at less than 10% by weight, i.e., "*Co-surfactants* consisting of *additional* anionic, nonionic, cationic, and amphoteric or zwitterionic surfactants can *also* be included, but typically comprise less than 10% by weight of the composition" (emphasis added). Prior to this limited disclosure, the '186 patent discloses innumerable surfactants at columns 22-27. The disclosure relating to co-surfactants relates to *additional* surfactants that *also* can be included with a surfactant. Accordingly, the examiner's reliance on column 27, lines 56-59 is misplaced. Moreover, the '186 patent fails to disclose a composition essentially (a) free of a surfactant, (b) free of a metal salt, *and* (c) free of a second antimicrobial agent. The examiner's reasoning is an example of hindsight reconstruction wherein an isolated statement is used to support a rejection without a consideration either of the claimed invention as a whole or the *complete* teachings of the reference.

In addition, Example 21 does not "suggest" high levels of surfactants. To be precise, Example 21 *explicitly teaches* 5.0% ammonium lauryl sulfate and 5.0% ammonium laureth-3 sulfate, or 10.0% total surfactant, by weight. This is *50* times the claimed maximum of surfactant.

At page 5 of the Office Action, paragraph 12, the examiner states:

> "The examiner contends that a reference does not need to teach each of the components in an example to be indicative of obviousness. The general teaching of Beerse et al states that metal –salt complex is not require [sic] to perform as suggested (col. 47, lines 18-55). Moreover, Beerse et al teach several embodiments that do not require surfactants (see examples 4, 12, 14-15, 16-18)."

The examiner appears to be saying that as long as individual ingredients of a composition can be found in a reference, then a claim can be found obvious. In looking at different embodiments of the '186 patent, the examiner is focusing on individual ingredients that may or may not be present, then adding the various ingredients together or deleting ingredients, to arrive at a conclusion of obviousness. The examiner has failed to clearly articulate *facts* as to the way the claimed invention "as a whole" would have been obvious to a person skilled in the art. In particular, the examiner has failed to consider the claimed invention as a whole, as opposed to its individual ingredients, and has failed to consider the unpredictability in the art, wherein changing the identity of an ingredient, or its actual or relative amount in a composition, can substantially influence antimicrobial efficacy. For example, see the examples in the present application. While the examiner appears to rationalize his conclusion of obviousness, the examiner does not articulate facts to support the asserted rationale. MPEP §2143.

The examiner is "cherry picking" individual ingredients from various portions and examples of the '186 patent without considering either the entire teaching of the embodiments in the '186 patent or the claimed invention as a whole. The sole explicit teaching of a composition that is free of a metal salt in the '186 patent (Example 21) contains 10 wt % of a surfactant and 1.5 wt. % of a second antimicrobial agent, *both* of which are excluded from the present claims. The examples relied upon by the examiner (i.e., 4, 12, and 14-18) *all* are free of a surfactant, but all *contain* a metal salt, which is excluded from the present claims.

In general, the examiner's reasoning also is inconsistent. To support exclusion of a metal salt, the examiner relies upon the limited general teachings of the '186 patent at column 47, lines 18-55, but neglects the specific teaching on Example 21. However, to support exclusion of a surfactant, the examiner neglects the extensive general teachings at *columns* 22-27 of the '186 patent to include a surfactant, but relies upon specific examples to exclude a surfactant. Overall, it is submitted that the '186 patent would *not* have *reasonably* suggested to a person skilled in the art to (a) exclude a second antimicrobial agent *and* (b) exclude surfactants *and* (c) exclude a metal salt *and* (d) include a sufficient amount of hydric solvent to provide a log reduction of at least 3 against *S. aureus* and/or *E. coli* after 30 seconds contact.

The examiner contends that testing against comparative examples is necessary to support patentability. At page 5 of the Office Action, paragraph 13, the examiner states:

> "13. The Declaration under 37 CFR 1.132 filed 7-25-2008 is insufficient to overcome the rejection of claims2-3 [sic], 5-6, 9, 11-26 based upon Beerse et al as set forth in the last Office action because: Declarant states an opinion of Beerse et al that is not supported by factual evidence which compares the closest prior art of record against the claimed invention."

However, appellants are not claiming an improvement over the '186 patent, but are claiming a method using an entirely different composition. The '186 patent contains no objective evidence of efficacy, but merely a definition of "residual antibacterial activity" at column 4, lines 22-39, and "Analytical Methods" at columns 44-46. However, even assuming *arguendo* that the '186 patent compositions are efficacious, comparing the present compositions to the '186 patent composition would serve little purpose. The compositions of the '186 patent arguably would be shown to be efficacious, and appellants already have shown that the claimed compositions are efficacious.

The present invention is a discovery that, contrary to the '186 patent, the claimed composition is efficacious in the *absence* of a metal salt, in the *absence* of a surfactant, and in the *absence* of any other second antimicrobial agent. The '186 patent fails to lead, or provide any apparent reason for, a person skilled in the art to make these multiple jumps in reasoning, and *then* include a sufficient amount of a claimed hydric solvent to provide the claimed log reduction of *S. aureus* and/or *E. coli* after 30 seconds contact.

More particularly, the present invention is demonstrated in the examples, wherein it is shown that an aromatic carboxylic acid or a hydric solvent *alone* does not provide a high antimicrobial efficacy, as claimed. Both the aromatic carboxylic acid and hydric solvent are needed to achieve a high antimicrobial efficacy, and a sufficient amount of the hydric solvent also is needed (see specification, Example 4).

In effect, appellants *have* provided comparative testing to the closest prior art. If one takes a composition from the '186 patent, and following the examiner's strained reasoning, then excludes the metal salt *and* a surfactant *and* any other second antimicrobial

agent, the resulting composition would be those tested in Examples 1, 3, and 4. These examples show that simply excluding one or more of these components does *not* provide a composition having the claimed efficacy. What is needed is a combination of aromatic carboxylic acid and a sufficient amount of hydric solvent, as claimed. It was appellants that made the inventive discovery of including a hydric solvent in the claimed amounts to provide a highly efficacious composition for use in the claimed method. This discovery is neither taught nor suggested in the '186 patent.

The presently claimed invention clearly exhibits unexpected results, even when the essential metal salt of the '186 patent is omitted. In particular, the present examples show an unexpectedly high antimicrobial efficacy when both an aromatic carboxylic *and* a claimed hydric solvent are present (see Examples 1, 4, 7, and 9). Comparative Examples 2 and 3 show that both the aromatic carboxylic acid *and* hydric solvent are needed to achieve a high antimicrobial efficacy.

At page 6 of the Office Action, the "examiner contends that the general teaching of Beerse et al. states that the metal-salt complex is not require [sic] to perform as suggested". However, the only disclosure of the '186 patent supporting the statements at column 47, lines 18-54, is Example 21, wherein a *second* antimicrobial agent, i.e., PCMX, is utilized to enhance the antimicrobial activity of the benzoic acid analog. The substantial differences between Example 21 of the '186 patent and the present compositions are set forth above, and in the Seitz Declaration (Evidence Appendix, paragraphs 7-16), showing that the comparison between a composition of the '186 patent and a claimed composition would be meaningless.

The differences between present claims and the '186 patent would not have been obvious to a person skilled in the art under 35 U.S.C. §103. In fact, the '186 patent fails to support a *prima facie* obviousness rejection over the present claims. Simply put, the '186 patent provides no apparent reason to modify the '186 patent as suggested by the examiner with any reasonable expectation of providing an efficacious antibacterial method. The '186 patent stresses the necessity of either including a metal salt or using another second antimicrobial agent in the composition in order to achieve an enhanced antimicrobial action. For example, the '186 patent includes 42 examples, of which 41 contain a metal salt as an

antimicrobial component. The sole example in the '186 patent omitting a metal salt, i.e., Example 21, contains a high percentage of anionic surfactant *and* is lacking a hydric solvent *and* contains a second antimicrobial agent. The '186 patent fails to teach or suggest a composition that (a) omits a metal salt and other additional antimicrobial agents, *and* (b) is essentially free of a surfactant, *and* (c) includes a hydric solvent, as presently claimed. From the teachings of the '186 patent, a person skilled in the art would not have had any apparent reason to omit a metal salt *and* omit a surfactant *and* include a claimed hydric solvent with any reasonable expectation of providing a useful antimicrobial composition.

To establish a *prima facie* case of obviousness, *all three* requirements recited in MPEP §2143 must be satisfied: (1) the prior art reference or combination of references must teach or suggest *all the limitations* of the claims to those of ordinary skill in the art. See *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."); (2) the prior art relied upon must contain some suggestion or incentive, coupled with knowledge generally available in the art at the time of the invention, that would have motivated those of ordinary skill in the art to modify a reference or combine the references. See, *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385, 58 USPQ2d 1286, 1293 (Fed. Cir. 2001) ("in holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in a way that would produce the claimed invention."); *and* (3) the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made.

In the present application, the '186 patent fails to teach or suggest all the limitations of the claims to those of ordinary skill in the art, i.e., an aromatic carboxylic acid as the sole antimicrobial agent, the claimed minimum amount of dipropylene glycol, and the claimed amount of surfactant.

The '186 patent also fails to provide an apparent reason to modify the teachings of the reference and arrive at the present invention. The '186 patent has a limited disclosure that a metal ion can be excluded from the composition, but the reference fails to

teach that an aromatic carboxylic acid can be used as the sole antimicrobial agent. The '186 patent explicitly teaches using a second antimicrobial agent when the metal ion is excluded. The '186 patent also teaches using a high amount of surfactant in the absence of a metal ion, and fails to teach dipropylene glycol in the absence of a metal ion. Also see Seitz Declaration, Evidence Appendix, paragraphs 8-18.

The proposed modifications of the '186 patent to arrive at the present invention also would not have a reasonable expectation of success, as seen through the eye of a person skilled in the art. See Seitz Declaration, Evidence Appendix, paragraph 18.

The '186 patent therefore fails to meet the criteria set forth as MPEP §2143, and accordingly, a *prima facie* case of obviousness has not been made and the rejection should be withdrawn.

In summary, persons skilled in the art simply would not be motivated make the several jumps in reasoning needed to arrive at the presently claimed invention after reading the '186 patent. Therefore, in view of the substantial differences between the '186 patent and the present claims, it is submitted that the rejection of the pending claims as being obvious over the '186 patent under 35 U.S.C. §103 should be reversed.

IX. CONCLUSION

In view of the foregoing remarks, appellants respectfully request that the Board reverse the final rejection of claims 2, 3, 5, 6, 9, and 11-26, and that all pending claims should be allowed.

Dated: February 9, 2009

Respectfully submitted,

By _____

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CLAIMS APPENDIX

Claims on Appeal in Application Serial No. 10/720,862

1. (Cancelled)

2. (Previously presented) The method of claim 17 comprising about 0.1% to about 5%, by weight, of the aromatic carboxylic acid.

3. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid has a pKa of about 2.5 to about 7.

4. (Cancelled)

5. (Previously presented) The method of claim 17 wherein the aromatic carboxylic acid is selected from the group consisting of salicylic acid, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, *o*-bromobenzoic acid, *m*-bromobenzoic acid, *o*-chlorobenzoic acid, *m*-chlorobenzoic acid, *p*-chlorobenzoic acid, 2,4-dihydroxybenzoic acid, 2,5-dihydroxybenzoic acid, 3,4-dihydroxybenzoic acid, 3,5-dihydroxybenzoic acid, ethylbenzoic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic acid, *o*-iodobenzoic acid, *m*-iodobenzoic acid, methyl-*o*-aminobenzoic acid, methyl-*m*-aminobenzoic acid, methyl-*o*-aminobenzoic acid, *o*-phenylbenzoic acid, isopropylbenzoic acid, and mixtures thereof

6. (Previously presented) The method of claim 17 wherein the antimicrobial agent comprises salicylic acid, *m*-hydroxybenzoic acid, *p*-hydroxybenzoic, *o*-aminobenzoic acid, *m*-aminobenzoic acid, *p*-aminobenzoic acid, or a mixture thereof.

7. (Cancelled)

8. (Cancelled)

9. (Previously presented) The method of claim 17 wherein the hydric solvent consists of about 20% to about 35%, by weight, dipropylene glycol.

10. (Cancelled)

11. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from the group consisting of methanol, ethanol, isopropyl alcohol, n-butanol, n-propyl alcohol, ethylene glycol, propylene glycol, glycerol, diethylene glycol, tripropylene glycol, hexylene glycol, butylene glycol, 1,2,5-hexanetriol, sorbitol, PEG-4, and mixtures thereof.

12. (Previously presented) The method of claim 17 wherein the composition further comprises additional solvents selected from isopropanol, ethanol, and a mixture thereof.

13. (Previously presented) The method of claim 17 wherein the pH-adjusting compound is present in an amount of about 1% to about 5%, by weight, of the composition.

14. (Previously presented) The method of claim 17 having a pH of about 2 to about 5.

15. (Previously presented) The method of claim 17 wherein the pH-adjusting compound comprises sodium phosphate, sodium dihydrogen phosphate, disodium hydrogen phosphate, sodium hydroxide, potassium hydroxide, or a mixture thereof.

16. (Previously presented) The method of claim 17 comprising:

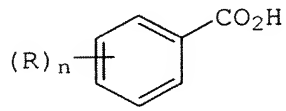
(a) about 0.2% to about 5%, by weight, of the aromatic carboxylic acid as the sole antimicrobial agent;

(b) about 10% to about 40%, by weight, of dipropylene glycol;

(c) a sufficient amount of the pH-adjusting compound to provide a pH of about 2.25 to about 5.

17. (Previously presented) A method of reducing a bacteria population on a surface comprising contacting the surface with an antimicrobial composition for 30 seconds to achieve a log reduction of at least 3 against *S. aureus* or a log reduction of at least 3 against *E. coli*, wherein the antimicrobial composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

18. (Original) The method of claim 17 wherein the composition achieves a log reduction of at least 3 against *S. aureus* and a log reduction of at least 3 against *E. coli*.

19. (Original) The method of claim 17 wherein a log reduction of at least 3 is achieved in a viral population.

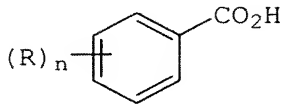
20. (Original) The method of claim 19 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

21. (Original) The method of claim 17 wherein the surface is a skin of a mammal.

22. (Previously presented) A method of reducing a viral population on a surface comprising contacting the surface with a composition of for 30 seconds to achieve a viral log reduction of at least 3,

wherein the composition comprises:

(a) about 0.1% to about 10%, by weight, of an aromatic carboxylic acid, wherein the aromatic carboxylic acid has a structure



wherein R, independently, is selected from the group consisting of hydroxy, C_{1-4}alkyl, C_{1-4}alkoxy, amino, halo, phenyl, and benzyl; and n is 1 or 2;

(b) about 10% to about 40%, by weight, of a hydric solvent comprising dipropylene glycol;

(c) a sufficient amount of a pH-adjusting compound to provide a pH of about 2 to about 5.5; and

(d) a carrier comprising water,

wherein the aromatic carboxylic acid is the sole antimicrobial agent in the composition,

and the composition contains 0% to 0.2%, by weight, of a surfactant.

23. (Original) The method of claim 22 wherein the viral population comprises Rhinovirus 1A, Rhinovirus 2A, Rotavirus Wa, and mixtures thereof.

24. (Original) The method of claim 22 wherein the surface is a skin of a mammal.

25. (Previously presented) The method of claim 16 wherein the antimicrobial carboxylic acid comprises salicyclic acid.

26. (Previously presented) The method of claim 16 wherein the composition further comprises additional solvents selected from ethanol, isopropanol, and mixtures thereof.

EVIDENCE APPENDIX

Declaration of Earl P. Seitz under 37 C.F.R. §1.132, filed July 25, 2008.

Docket No.: 29475/39204
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Timothy J. Taylor et al.

Application No.: 10/720,862 | Confirmation No.: 5172

Filed: November 24, 2003 | Art Unit: 1751

For: Antimicrobial Compositions Containing an Aromatic Acid and a Hydric Solvent | Examiner: N. Ogden

DECLARATION OF EARL P. SEITZ UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

NOW COMES EARL P. SEITZ, Declarant herein, and states as follows:

1. I am a coinventor of the invention disclosed and claimed in the above-identified patent application.

2. I have been employed by The Dial Corporation (Dial), Scottsdale, Arizona, since 1978. I was a Research Manager of various technology and product development groups at Dial from 1980 to 1994. I am presently a Research Fellow at Dial, and have held this position since 1994. I am engaged in the research and development of personal care products, including compositions containing topically active components. In 2001, I was awarded Dial's R&D's highest technical award, the Robert E. Casely Award for Excellence in Innovation.

3. I received a Ph.D. in organic chemistry from Oregon State University, Corvallis, Oregon (1977), and a B.S. in chemistry from Texas Christian University, Fort Worth, Texas (1968). I also served in the U.S. Navy from 1969-1972, and held a post-doctoral position at The University of Wisconsin, Madison, WI in 1977 and 1978.

4. I have conducted research in the fields of skin cleansers and related surfactant-based compositions, including topically active and antibacterial compositions. I am a named inventor on seven U.S. patents involving technology disclosed in the above-identified patent application.

5. I have read and understand the Office Action dated March 28, 2008, which was issued in connection with U.S. Patent Application Serial No. 10/720,862. I also have read and understand the following patent cited by the examiner in U.S.S.N. 10/720,862: Beerse et al. U.S. Patent No. 6,294,186 ('186)).

6. Claims 2, 3, 5, 6, 9, and 11-26, all of the claims in the application, have been rejected as being obvious over the '186 patent. The basis of this rejection is that a skilled person would expect the claimed compositions to exhibit a similar antibacterial activity to compositions of the '186 patent because the '186 patent teaches the "same" ingredients. Contrary to the examiner's assertion, the compositions disclosed in the '186 patent are substantially different from the compositions recited in the presently-claimed methods.

7. The '186 patent describes and claims compositions comprising an antimicrobial agent. The title of the specification of the '186 patent is "Antimicrobial Compositions Comprising a Benzoic Acid Analogue and a Metal Salt". The '186 patent explicitly teaches that the metal salt contributes to the antimicrobial activity. For example, the '186 patent states that "[W]ithout being limited by theory, it is believed that the compositions of the present invention, the benzoic acid analog and metal salt complex to form a metal-acid complex which has been found to provide the synergistic immediate and residual anti-viral and anti-bacterial efficacy to surfaces to which such compositions are applied" ('186 patent, column 7, lines 60-65).

8. The '186 patent contains 42 examples. Of these 42 examples, 41 contain a metal salt as an antimicrobial agent in addition to the aromatic carboxylic acid.

9. The '186 patent also discloses a second embodiment wherein the composition contains a benzoic acid analog and a dermatologically effective carrier, and is essentially free of metal salts. This embodiment is identified by one sole example, namely

Example 21 in the '186 patent. However, the composition of this example also contains a total of 10 weight per cent of surfactants and 1.50% para-chloro-meta-xylenol, which is a second antimicrobial agent.

10. With regard to a hydric solvent, the '186 patent recites that a carrier for the disclosed composition can be an alcohol (see for example, column 9, lines 33-54 of the '186 patent). The sole disclosure in the '186 patent of dipropylene glycol, as claimed in the present invention, is in Examples 16 to 18. In these examples, the amount of dipropylene glycol is 8% by weight. Examples 16 to 18 of the '186 patent also include a metal salt, which is excluded from the present claims.

11. As stated above, the presently claimed composition includes aromatic carboxylic acid as the *sole* antimicrobial agent, an amount of hydric solvent, and 0% of 0.2% by weight of a surfactant. Having read the '186 patent, I can find no disclosure or suggestion that would lead a person skilled in the art to the presently claimed composition.

12. Moreover, the '186 patent *explicitly* teaches that the metal salt is an essential ingredient in the first embodiment of the invention, and that the metal salt contributes to antimicrobial activity. In contrast to the '186 patent, the present claims exclude the presence of a metal salt that is taught as essential in the '186 patent.

13. In the second embodiment of the '186 patent, a metal salt is absent. However, the sole example of this embodiment, i.e., Example 21, differs in three substantial ways from the presently claimed composition. Firstly, although the composition of Example 21 is free of a metal salt as a second antimicrobial agent, the composition contains 1.50% by weight of the additional antimicrobial agent para-chloro-meta-xylenol (PCMX), i.e., a phenolic antimicrobial agent. This antimicrobial agent is excluded from the claims of the patent application in suit, i.e., it is not an aromatic carboxylic acid.

14. Secondly, Example 21 in the '186 patent contains a high amount of surfactant (10 weight per cent). In contrast, the present claims recite a composition having 0% to 0.2% by weight of a surfactant. Thirdly, Example 21 of the '186 patent is free of a hydric solvent, which is required in the claims of the application.

15. In summary, it is my opinion that the '186 patent teaches that a metal salt is essential to provide a synergistic effect, as a second microbial agent together with a first aromatic antimicrobial agent. As a skilled person, when reading this document I am told that the metal salt is essential for performing the invention of the '186 patent. In view of the teaching of the '186 patent that the metal salt provides a synergistic effect, it would be my belief on reading this document that omitting the metal salt would cause the invention of the '186 patent to fail, i.e., not provide sufficient antimicrobial action. Further, if a metal salt is excluded, the '186 patent then teaches me that a different second antimicrobial agent, e.g., PCMX, must be present to be efficacious, as in Example 21 of the '186 patent.

16. However, the disclosure of the '186 patent is inconsistent and has one example in which the metal salt is omitted, despite the fact that the document appears to be geared toward compositions containing a metal salt. However, this embodiment is substantially different from the composition of the present claims and it is meaningless to compare Example 21 with the compositions of the invention, given that the example is so different from the claimed invention. Moreover, Example 21 also contains a further antimicrobial agent to provide an enhanced antimicrobial effect in view of the absence of a metal salt.

17. The efficacy of the present invention is demonstrated by the examples in the specification. Examples 1-3 show that pH is important to enhance efficacy (Ex. 1), that a hydric solvent alone is not efficacious (Ex. 2), and that an aromatic carboxylic alone, i.e., in the absence of a hydric solvent, is not efficacious.[1] Example 4 shows that a minimum amount of hydric solvent is required to achieve a log reduction of at least 3, as claimed. Example 9 shows that the method and composition are highly effective in reducing viral populations.

18. These efficacious results are achieved by using compositions free of a metal salt, essentially free of a surfactant, and containing an aromatic carboxylic acid as the sole antimicrobial agent in the composition. A person skilled in the art, after reading the '186 patent, would not have considered making any of these modifications, let alone all three, and still expect to provide a log reduction against *S. aureus* and/or *E. coli* of at least three.

[1] Efficacy is measured as a log reduction against *S. aureus* and/or *E. coli* of at least 3 after 30 seconds contact.

19. The compositions claimed in the present application require a sole antimicrobial agent and is essentially free of an optional surfactant. The inventors of the present application have determined using their inventive skill that an antimicrobial composition can be effective using a sole antimicrobial agent without the mandatory metal salt of the '186 patent (to provide synergistic activity) or a second antimicrobial agent. Despite not having *either of* these ingredients, the claimed compositions are surprisingly effective.

20. The use of a single antimicrobial agent in the present application is an advantage, not least in terms of the resulting commercial product and ease of production of the product.

21. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; further, these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Dated: 24 JULY, 2008

Earl P. Seitz

RELATED PROCEEDINGS APPENDIX

There are no related proceedings.